AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 79 Monday,
No. 188 September 29, 2014

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 117, and 507

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 117, and 507

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our 2013 proposed rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. In that 2013 proposed rule, we proposed to add CGMP requirements for animal food and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. We are taking this action because the input we have received from public comments has led to significant changes in our current thinking on certain key provisions of this proposed rule. We are reopening the comment period only with respect to specific issues identified in this proposed rule.

DATES: Submit either electronic or written comments on the proposed rule by December 15, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 15, 2014 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No 2011–N–0922 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9207, email: *kim.young@fda.hhs.gov.*

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Executive Summary

Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking

We previously proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals, as required by the FDA Food Safety Modernization Act (FSMA). The proposed requirements would apply to establishments that are required to register with us as an animal food ''facility.'' In this document we are proposing to revise several previously proposed requirements, taking into account the comments we have reviewed so far for the proposed rule for preventive controls for food for animals and the proposed rule for preventive controls for human food, because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions.

In the 2013 proposed rule, we asked for comment on when and how three provisions (i.e., product testing programs, environmental monitoring programs, and supplier programs) are an appropriate means of implementing the statutory directives of FSMA. We also requested comment on whether a facility should be required to address potential hazards that may be intentionally introduced for economic reasons. Some comments received to the 2013 proposed rule assert that additional public comment is warranted before consideration is given to whether a final rule includes or does not include provisions that were discussed in the 2013 proposal but for which we had not included regulatory text in the 2013 proposal. In this document we are providing an opportunity for such public comment on potential requirements for product testing programs, environmental monitoring programs, and supplier programs, and hazards that may be intentionally introduced for purposes of economic gain, which take into account the comments we have reviewed so far. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In the 2013 proposed rule, we requested comment on three options for classifying a facility as a ''very small business,'' with consequences for facilities in terms of eligibility for exemptions and the timeframe to comply with this rule. In this document we are proposing a definition for ''very small business'' (i.e., a business that has less than $2,500,000 in total annual sales of animal food adjusted for inflation).

We are proposing a revised version of the 2013 proposed current good manufacturing practice regulations. In addition, we added a section to the proposed current good manufacturing practice regulations for holding and distribution of human food by-products for food for animals. This would apply to human food facilities that hold and distribute by-products from the human food production that are used for food for animals.

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

The previously proposed (2013) current good manufacturing practice requirements (CGMPs) were based, in general, on FDA's existing human food CGMP regulations. The revised proposed CGMPs for food for animals would establish baseline standards for producing safe animal food that are more applicable to the animal food industry and that provide flexibility for the wide diversity in types of animal food facilities. Human food processors already complying with FDA human food safety requirements would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a by-product, except those proposed for the holding and distribution of certain human food by-products for food for animals (e.g., ensuring by-product is not co-mingled with garbage). Under the revised proposal, all other requirements of part 507, including the hazard analysis and preventive controls requirements, would not apply to these by-products of human food production.

The previously proposed requirements for hazard analysis and risk-based preventive controls applied a construct previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on critical control points to control hazards that are ''reasonably likely to occur.'' We are proposing to eliminate the term ''hazard reasonably likely to occur'' throughout the proposed requirements to reduce the potential for a misinterpretation that all necessary preventive controls must be established at critical control points (CCPs). The revised regulations would use a new term (''significant hazard'') in its place.

The defined term ''significant hazard'' would be linked to the facility's hazard analysis, which addresses risk (i.e., both the severity of a potential hazard and the probability that the hazard will occur). Thus, this term would reflect the risk-based nature of the requirements. In addition, the revised regulations would provide additional flexibility relative to the previous proposal by providing that a facility can take into account the nature of a preventive control in determining when and how to establish and implement appropriate preventive control management components,

including monitoring, corrections or corrective actions, verification, and records. Table 6 in the document provides examples of flexibility provided by the rule, including flexibility provided for a facility to take into account the nature of the preventive control when determining the appropriate preventive control management components.

The potential product testing provisions would, if included in a final rule, require that a facility conduct product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control. The facility would be required to have written procedures for product testing, corrective action procedures to address the presence of a pathogen or appropriate indicator organism in finished animal food detected as a result of product testing, and records of product testing.

The potential environmental monitoring provisions would, if included in a final rule, require that a facility conduct environmental monitoring as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control if contamination of finished animal food with an environmental pathogen is a significant hazard. The facility would be required to have written procedures for environmental monitoring, corrective action procedures to address the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring, and records of environmental monitoring.

The potential supplier program would, if included in a final rule, require supplier controls when the facility's hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient (e.g., if a supplier tests a mineral mix for dioxin that a facility would use to manufacture finished cattle feed). A facility would not need to establish supplier controls if it controls that hazard, or if its customer controls that hazard. The supplier program would be written. With one exception, the receiving facility would have flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier's food safety records; or other appropriate verification activity). The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In this circumstance, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter, unless the receiving facility determines and documents that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

The proposed requirements regarding potential hazards that may be intentionally introduced for economic reasons would, if included in a final rule, require that a facility consider in its hazard analysis hazards that may be intentionally introduced for purposes of economic gain.

We seek comment on whether these potential requirements discussed above should be included in a final rule.

The previously proposed requirements provided for an exemption for certain facilities defined by FSMA as ''qualified facilities.'' As required by FSMA, the previously proposed requirements also included an administrative procedure whereby we could withdraw that exemption under certain circumstances. In this document, we are proposing a series of modifications to the proposed withdrawal provisions. These modifications include describing the steps we would take before withdrawing an exemption, including advance notification to the facility; a procedure for re-instatement of a withdrawn exemption; and an additional 60 days for a facility whose exemption is withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

Costs and Benefits

We summarize the domestic annualized costs of the proposed regulation with the revised provisions, including the potential requirements for product testing, environmental monitoring, a supplier program, and potential requirements regarding hazards that may be intentionally introduced for economic reasons, using a discount rate of 7 percent and discounted over a 10 year period in the following table. The revised proposed regulation uses a very small business definition of less than $2,500,000 of total annual sales of animal food, adjusted for inflation, and includes potential additional requirements that facilities subject to subpart C institute risk-based environmental monitoring, product testing, and a supplier program as appropriate to the animal food, the facility and the nature of the preventive controls, and controls to help prevent hazards associated with economically motivated adulteration. As described in the updated Preliminary Regulatory Impact Analysis (PRIA), for the final rule we anticipate making several modifications to our estimate of the cost of our proposed rule (Ref. 1) (see section XVIII). As with the original proposal, we lack sufficient data to quantify the potential benefits of this supplemental notice of proposed rulemaking.

A summary of the domestic costs and potential benefits of the original and supplemental proposed rules is shown in the following table.

ORIGINAL AND REVISED ESTIMATED TOTAL DOMESTIC COSTS BASED ON ADDITIONAL PROVISIONS

[Very Small Business Defined as Annual Animal Food Sales < $2.5 million]

	Total (million)
Original Total Annualized Costs without additional provisions	$65
Additional costs because of potential new provisions	4
Revised Total Annualized Costs	69
Benefits	(1)

1 Unquantified.

If foreign facilities are included, the total annualized cost of this supplemental notice of proposed rulemaking is estimated at $93 million.

I. Background

A. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables us to better protect public (human and animal) health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides us with new enforcement authorities to help achieve higher rates of compliance with risk-

based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and encourages us to form partnerships with State, local, tribal, and territorial authorities. Table 1 identifies three additional proposed rules, issued to implement FSMA, that we discuss in this document.

TABLE 1—PUBLISHED PROPOSED RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed rule for preventive controls for food for animals.	78 FR 64736, October 29, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed rule for preventive controls for human food.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed rule for produce safety	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed rule for FSVP	78 FR 45730, July 29, 2013.

B. 2013 Proposed Rule for Preventive Controls for Food for Animals

In the 2013 proposed rule for preventive controls, we:

- Proposed to add, in newly established part 507, regulations for Current Good Manufacturing Practice In Manufacturing, Processing, Packing, and Holding for Food for Animals (CGMPs);
- Proposed to add, in newly established part 507, requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for food for animals;
- Requested comment on when and how product testing programs, environmental monitoring programs, and supplier approval and verification are an appropriate means of implementing the statutory framework of FSMA; and
- Requested comment on whether a final rule should address potential hazards that may be intentionally introduced for economic reasons.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new part 507 as shown in Table 2:

TABLE 2—PROPOSED SUBPARTS IN NEW PART 507

Subpart	Title
A	General Provisions.
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Withdrawal of an Exemption Applicable to a Qualified Facility.
E	Reserved.
F	Requirements Applying to Records That Must be Established and Maintained.

In the 2013 proposed rule for preventive controls, we provided background discussing:

- The provisions of FSMA most directly applicable to the proposed requirements, particularly the statutory provisions of section 103 of FSMA (established in section 418 of the FD&C Act);
- Hazard Analysis and Critical Control Points (HACCP) Systems;
- Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding Food for Animal Consumption;
- The Role of Testing as a Verification Measure in a Food Safety System (including discussions about environmental monitoring as well as testing raw materials, ingredients, and finished product), largely in an Appendix to the 2013 proposed rule for preventive controls (the Appendix)); and
- The Role of Supplier Approval and Verification Programs in a Food Safety System (largely in the Appendix).

We also issued for public comment a ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft risk assessment) (78 FR 64428, October 29, 2013). The purpose of the draft risk assessment was to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk, when conducted in a facility co-located on a farm. We used the tentative conclusions of the draft risk assessment to propose to exempt animal food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls.

II. Public Comments

A. Opportunities for Public Comment

We requested comments on the 2013 proposed rule for preventive controls by February 26, 2014. We extended the comment periods for the 2013 proposed rule for preventive controls, its information collection provisions, and the draft risk assessment in response to several requests that we do so (see Table 3).

Since issuing the 2013 proposed rule for preventive controls, we conducted numerous outreach activities. Three public meetings were held to solicit oral stakeholder and public comments on the 2013 proposed rule for preventive controls, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed rule for preventive controls (see Table 3) (Ref. 2, Ref. 3, Ref. 4).

TABLE 3—LIST OF FEDERAL REGISTER PUBLICATIONS REGARDING THE 2013 PROPOSED RULE FOR PREVENTIVE CONTROLS

Description	Publication
2013 proposed rule for preventive controls, requesting comments by February 26, 2014	78 FR 64736, October 29, 2013.
Notice of availability of the draft risk assessment, requesting comments by February 26, 2014	78 FR 64428 , October 29, 2013.
Notice of public meetings (to be held in College Park, MD on November 21, 2013; in Chicago, IL on November 25, 2013; and, in Sacramento, CA on December 6, 2013) on the 2013 proposed rule for preventive controls.	78 FR 64425, October 29, 2013.
Notice extending comment period, until March 31, 2014 , for the 2013 proposed rule for preventive controls and its information collections provisions.	79 FR 6111, February 3, 2014.
Notice extending comment period, until March 31, 2014 , for the draft risk assessment	79 FR 6116 , February 3, 2014.

B. Overview of Public Comments on the 2013 Proposed Rule for Preventive Controls

We received more than 2100 submissions by the close of the comment period, each containing one or more comments. Submissions were received from diverse members of the public, including in part, human and animal food facilities; trade organizations; consulting firms; law firms; pet owners; consumers; consumer groups; Congress, Federal, State, local and tribal Government Agencies. Some submissions included signatures and statements from multiple individuals.

Comments address many provisions of the 2013 proposed rule for preventive controls, including our requests for comment on including additional provisions that we did not include in the proposed regulatory text. Comments from some pet owners for the most part indicated they were pleased that new requirements were being established for the manufacture of pet food and that these requirements were comparable to the requirements for human food, which were covered by the 2013 proposed rule for preventive controls for human food. Some comments questioned whether the proposed requirements reflected the reality of production of food for animals with a particular concern that the proposed risk-based approach focuses too heavily on pathogens and not enough on other potential hazards in food for animals. Some comments assert that additional public comment would be warranted before any consideration on whether a final rule should or should not include provisions discussed in the proposed rule, but for which we had not included proposed regulatory text, such as potential requirements for product testing, environmental monitoring, a supplier approval and verification program, and potential hazards that may be intentionally introduced for economic reasons. The comment period did not close until March 31, 2014; we are still actively reviewing the comments.

C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

In December 2013, we announced that we would propose revised rule language for key provisions of the 2013 proposed rule for preventive controls for human food. Because the 2013 proposed rule for preventive controls for food for animals is a companion rule to the proposed rule on human food, in March 2014, we announced our intent to publish revised language for the 2013 proposed rule for preventive controls for food for animals, as well (Ref. 5). Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to the 2013 proposed rule for preventive controls for human food. Many of the proposed provisions of the animal food preventive controls rule match those in the human food rule. Section IX and X discuss our reasons for changes to the proposed current good manufacturing practice regulations. Additional information regarding the basis of this supplemental notice of proposed rulemaking can be found in the supplemental notice of proposed rulemaking for preventive controls for human food.

III. Scope of the Supplemental Notice of Proposed Rulemaking and Our Request for Public Comment

In this document, we are proposing:

- Revisions to several definitions we proposed to apply to the requirements for hazard analysis and risk-based preventive controls, including definitions for ''environmental pathogen,'' ''reasonably foreseeable hazard,'' and ''very small business'';
- New definitions for ''significant hazard'' ''pathogen,'' and ''you'';
- Revisions to subpart B for current good manufacturing practice regulations to make the requirements more applicable for animal food facilities;
- To not subject human food by-products used for animal food by human food facilities that are subject to and in compliance with subpart B of proposed part 117 and other applicable human food safety requirements of the FD&C Act (and implementing regulations) for the human food if the by-products are not further processed at the facility to hazard analysis and preventive controls requirements and only require compliance for holding and distributing these by-products;
- Revisions to the proposed procedures that would govern withdrawal of an exemption from a ''qualified facility,'' including clarifications about the steps we would take before issuing an order to withdraw the exemption, an expanded timeframe for a facility to comply with an order withdrawing an exemption, and a mechanism for a withdrawn exemption to be re-instated;
- A series of revisions to the proposed requirements for hazard analysis and risk-based preventive controls (proposed subpart C) to:
- Emphasize the risk-based nature of the preventive controls and requirements for monitoring, corrective actions, and verification activities;
- Reduce the potential for misinterpretation that the rule requires that all necessary preventive controls be established at critical control points (CCPs) for all hazards that a facility addresses in its food safety plan;
- Change the wording in the ''Monitoring'' section to more closely match the language of the statute and the proposed rule for preventive controls for human food;
- Increase flexibility for a facility to determine, based on the nature of a preventive control, when requirements for ''preventive control management components'' (i.e., monitoring, corrective actions, and verification) are appropriate;
- Substitute the pronoun ''you'' for ''the owner, operator, or agent in charge of the facility'' throughout these proposed requirements;
- Substitute the term ''adequate'' (which is a term we proposed to define) in place of the term ''sufficient'' (which we did not propose to define);

• Improve readability, through rearrangement of some of the proposed regulatory text and editorial revisions (such as increased use of active voice).

In this document, we also are providing an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain, including definitions of terms (i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier'') that would be used in some of those potential requirements. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

We discuss these proposed requirements in sections V through XVI. Because several of the proposed revisions relate to the overall framework in subpart C for hazard analysis and risk-based preventive controls, we are including the complete regulatory text for proposed subpart C. However, in this document, we are reopening the comment period only with respect to the issues specified in this section III.

Importantly, the proposed revisions to the provisions we have included in the regulatory text are based on preliminary review of comments. We will complete our review of comments previously submitted and consider the comments responsive to this Legal and Regulatory Framework Under of proposed rulemaking in developing the final rule.

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

In the 2013 proposed rule for preventive controls for human food (78 FR 3646), we described the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations (21 CFR part 1, subpart H; the section 415 registration regulations). We focused on the framework that governs whether an establishment that grows and harvests crops satisfies the definition of ''farm'' because the facility registration requirements of section 415 of the FD&C Act do not apply to ''farms.'' When we implemented the statutory requirements for registration of food facilities, it established a definition for ''farm'' that first describes a farm as a facility devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both (§ 1.227; 68 FR 58894, October 10, 2003). Although that definition of ''farm'' then provides that farms also pack or hold food, it limits facilities that fall within the definition of ''farm'' to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Thus, under the current framework an establishment that is devoted to the growing and harvesting of crops, but also packs and holds food not grown or raised on that farm or on another farm under the same ownership, would fall outside the definition of ''farm'' and be required to register as a food facility. Because an establishment that is required to register as a food facility is subject to the requirements of section 418 of the FD&C Act, under the current framework a determination of whether an establishment devoted to the growing and harvesting of crops is subject to FSMA's requirements for hazard analysis and risk-based preventive controls depends, in part, on where the food that the establishment packs or holds is grown or raised.

Under the current framework, a key factor in whether an establishment falls within the definition of ''farm,'' even with respect to crops it grows and harvests itself, is whether the activities conducted by the farm fall within definitions of ''harvesting,'' ''packing'' or ''holding'' (which are within the ''farm'' definition). As discussed in the 2013 proposed rule for preventive controls for human food, section 103 of FSMA directs FDA to conduct rulemaking to clarify the on-farm manufacturing, processing, packing and holding activities that would trigger a requirement for a farm to register as a food facility and, thus, be subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3674). In the 2013 proposed rule for preventive controls for human food, we explained how the status of a food as a raw agricultural commodity (RAC) or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act. For further discussion see section IV of the preamble in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register.**

In sections V and VI, we discuss the proposed revised definitions for ''farm,'' ''harvesting,'' ''packing,'' and ''holding.''

V. The ''Farm'' Definition

We are reopening the comment period, in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register,** with respect to ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''.

A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

Consistent with the organizing principles regarding classification of activities on-farm and off-farm, in the proposed rule for preventive controls for human food (78 FR 3646), we proposed to define ''harvesting,'' as a new definition in §§ 1.227 and 1.328, to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on the farm on which they were grown or raised, or another farm under the same ownership, and that harvesting does not include activities that transform a RAC into a processed food. The proposed definition included examples of activities that would be harvesting. As a conforming change to the proposed definition of ''harvesting,'' we proposed, to revise the definition of ''farm'' in current §§ 1.227(b)(3) and 1.328 to delete examples of harvesting that currently appear in the ''farm'' definition.

We also proposed, in the preventive controls proposed rule for human food, to revise the definition of ''holding'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC into a processed food.

We proposed, in the preventive controls proposed rule for human food, to revise the definition of ''packing'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on a farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC into a processed food.

See section V in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register** for additional discussion RACs.

B. Proposed Revisions to the Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

In the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, we are proposing to revise the ''farm'' definition so that it would no longer limit establishments that fall within the ''farm'' definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised ''farm'' definition, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it packs and holds raw agricultural commodities grown on another farm. To limit the potential for confusion related to the term ''facility,'' we are proposing to substitute the term ''establishment'' for the term ''facility'' in the revised definition of ''farm.'' We also are proposing that the packing activities (which may include packaging) that it had proposed to include in the expanded definition of ''packing'' for farms and farm mixed-type facilities be included in the ''farm'' definition rather than in an expanded definition of ''packing.'' Under the revised ''farm'' definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the ''farm'' definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing. The proposed revised definition of ''harvesting'' would also include ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity.

For further discussion, please see section V in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

C. One General Physical Location

We received some comments on the 2013 proposed rule for preventive controls for human food stating that that farms throughout the country are now made up of multiple, often non-contiguous fields due to geographic and topographic conditions, local development patterns, and the fact that a single ''farm'' today often derives from multiple previous farms due to the need to achieve economic efficiencies. Some comments explain that as farm land increasingly is partitioned into smaller and smaller parcels through estate divisions or for other reasons, farmers purchasing land find that they are rarely able to purchase adjacent parcels. These comments ask us to modify or remove the phrase ''in one general location'' in the ''farm'' definition.

During the rulemaking to establish the ''farm'' definition in the section 415 registration regulations, we explained that a farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens (68 FR 5378 at 5381, February 3, 2003). However, we did not propose to include this explanatory sentence in the regulatory text. Comments addressing ''one general physical location'' focused on how specifying ''in one general physical location'' would affect whether the farm would be subject to the section 415 registration regulations. Our response to those comments focused on the nature of the activities being conducted rather than on the contiguous or non-contiguous nature of parcels of land or nets (68 FR 58894 at 58906, October 10, 2003).

The definition of ''facility'' in the section 415 registration regulations likewise specifies that a facility means ''any establishment, structure, or structures under one ownership at one general physical location . . .'' However, this definition specifically adds an explanatory statement that a facility may consist of one or more contiguous structures (§ 1.227). During the rulemaking to establish this definition of ''facility,'' we explained that we proposed to include this explanatory sentence in the regulatory text as a result of comments that we received during our early outreach efforts (68 FR 5378 at 5381, February 3, 2003).

We are requesting comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition. Elsewhere in this issue of the **Federal Register**, in the supplemental notice of proposed rulemaking for preventive controls for human food, we are also requesting comment on the phrase ''in one general physical location'' in the ''farm'' definition. In responding to our request for comment on this issue, we ask commenters to carefully consider what, if any, impacts removing or modifying this phrase could have on other rules that already include (or have proposed to include) the same definition of ''farm'' as would be established in the section 415 registration regulations, as well as how such impacts would best be addressed. Please see section V.E in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register** for further discussion on this issue.

D. Feed Mills Associated With Contract and Fully Vertically Integrated Farming

We received some comments requesting clarification of whether all feed mills associated with contract farming or fully vertically integrated farming models would be required to comply with the proposed rule.

We are aware that there are a variety of farming models for raising animals. In one model, often referred to as contract farming, one entity owns the feed mill and the animals, but contracts with another entity that owns the establishment devoted to raising the animals. In this model, the feed mill would not be considered part of a farm under the current definition in 21 CFR 1.227 (see 68 FR 58894 at 58907 (Oct. 10, 2003) and 68 FR 5378 at 5382 (Feb. 3, 2003)). The feed mill also would not be considered part of a farm under the proposed revised definition of farm in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**. Therefore, the feed mill would be required to register as a food facility under section 415 of the FD&C Act and would be subject to the proposed rule for preventive controls.

In a second model, often referred to as fully vertically integrated farming, one entity owns the feed mill, the animals, and the establishment devoted to raising the animals. In this model, the feed mill would be considered part of a farm under the current definition in 21 CFR 1.227 (68 FR 58894 at 58907), and the proposed revised definition. Therefore, the feed mill would be exempt from registering as a food facility under section 415 of the FD&C Act and would not be subject to the proposed rule for preventive controls rule.

Cooperative farming is another model and depending on how the cooperative is structured, it can resemble the contract model or the fully vertically integrated model. How the cooperative is structured determines whether the

feed mill is required to register as a food facility under section 415 of the FD&C Act.

We have no evidence that the safety of animal food varies depending on whether a feed mill is associated with vertically integrated or contract farming. Therefore, we are asking for comment on whether feed mills associated with fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition (current or proposed revision) should be required to register as a food facility under section 415 of the FD&C Act. If so, how should we revise the farm definition so the feed mills associated with these fully vertically integrated farming operations would not be considered farms, would be required to register under section 415, and thus would be subject to the proposed rule. Registration under section 415 of the FD&C Act would also subject these feed mills to additional statutory requirements under the FD&C Act, for example, recordkeeping requirements under section 414, requirements for the Reportable Food Registry under section 417, and requirements for mandatory recall under section 423.

If these fully vertical farming feed mills would be required to register under section 415 of the FD&C Act, we also request comment on whether there should be an exemption from registration under section 415 for some of these feed mills based on size, such as number of animals being fed or the amount of animal food being fed (based on tonnage, monetary value, or some other factor).

Under the fully integrated vertical farming operations and certain contract farming operations, there would be no total annual sales figure for the animal food that could be used to determine whether a facility is a qualified facility (and thus exempt from proposed subpart C). With regard to these feed mills, we request comment on how to value the animal food being fed to animals for purposes of determining whether the feed mill would be a qualified facility (proposed § 507.7) and in particular a very small business. Qualified facilities would be exempt from the requirements of subpart C (hazard analysis and risk-based preventive controls).

VI. Definitions of ''Holding'' and ''Packing''

A. 2013 Proposed Definition of ''Holding''

In the 2013 proposed rule for preventive controls for human food, we proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 (see section V.A).

B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''

We proposed two exemptions directed to facilities ''solely engaged'' in the storage (i.e., holding) of certain types of animal food, and explained our reasons for doing so.

First, we proposed to exempt facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing from the requirements for hazard analysis and risk-based preventive controls, and explained our reasons for proposing to do so (proposed § 507.5(g); see discussion at 78 FR 64736 at 64764). We intended this provision to exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans) from the requirements for hazard analysis and risk-based preventive controls, provided that such facilities do not conduct other activities subject to FSMA's requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64764).

Second, we proposed to exempt a ''facility solely engaged in the storage of packaged food for animals that is not exposed to the environment'' from the requirements for hazard analysis and risk-based preventive controls that would be established in subpart C (proposed § 507.10(a); see discussion at 78 FR 64736 at 64768). We intended this provision to exempt, for example, facilities that store packaged animal food in containers in a warehouse. However, a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens would be subject to modified requirements (see proposed §§ 507.10(b) and 507.51.

In this section of this document, we are proposing revisions to the definition of ''holding'' in addition to the revisions, discussed in section V.B, that would be conforming amendments in light of the revised ''farm'' definition. In this section of this document, we are reopening the comment period with respect to the revised definition of ''holding'' (proposed § 507.3).

C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing

Some comments support for the proposed exemption for a facility solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. However, some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, that the proposed definition of ''holding'' would preclude facilities such as grain elevators from being eligible for the exemption in proposed § 507.5(g) because most such facilities conduct a variety of activities in addition to ''storage.'' For example, grain elevators typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of safe or effective storage or for meeting customer specifications:

- Fumigate grain to control pest infestation during storage;
- Clean grain using various mechanisms (sifting, sieving, and screening);
- Convey grain throughout the facility;
- Dry grain received with high moisture content; and
- Blend lots of grain.

Some comments recommended that we modify the proposed definition for ''holding'' to (1) encompass activities performed for the safe or effective storage of RACs (such as drying, screening, conditioning, and fumigating) off-farm and (2) encompass activities performed on RACs as a practical necessity for product distribution (such as blending different lots of the same commodity to meet a customer's quality specifications).

D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Some comments received during the public meetings for the 2013 proposed rule for preventive controls for animal food and received under the 2013 proposed rule for preventive controls for human food support the proposed exemption for a facility ''solely engaged in the storage of packaged food that is not exposed to the environment.'' These comments note that warehouses typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of storage or for product distribution, including:

- Affix tracking labels;
- Transport to a storage location in the warehouse;
- Hold non-food products, including toys and grooming aids for pets;
- Break down pallets of packaged animal food for distribution to the retail level in less-than-pallet quantities;
- Assemble ''sales kits'' for use in fundraising drives;
- Assemble variety packs by packing; and
- Use packaged food to build store displays.

Some of these comments we received recommend that we modify the proposed definition for ''holding'' to encompass activities that are performed on packaged food that is not exposed to the environment (1) incidental to storage of the animal food (such as transport and storage of non-animal food products); and (2) as a practical necessity for product distribution (such as affixing tracking labels, breaking down pallets, assembling sales kits and variety packs, and building store displays).

E. Proposed Revisions to the Definition of ''Holding''

Taking into account the comments we have reviewed so far for the 2013 proposed rules for preventive controls, we tentatively conclude that we should revise the definition of ''holding'' to encompass activities performed incidental to storage of animal food (e.g., activities performed for the safe or effective storage of that animal food and activities performed as a practical necessity for the distribution of that animal food). In addition to the activities specifically identified in the comments, we are aware of other activities (Ref. 6) that can be considered incidental to storage of RACs, either for the purposes of safe or effective storage or for meeting customer specifications, including:

- Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;
- Using modified atmosphere treatments to control pests;
- Using biological controls for pests;
- Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;
- Weighing grain;
- Sampling and grading grain; and
- Aerating grain to control temperature.

In this document, we are proposing to revise the definition of holding to:

- Clarify that holding also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food and activities performed as a practical necessity for the distribution of that animal food (such as blending of the same commodity));
- Broaden ''activities . . . performed for the safe or effective storage of raw agricultural commodities'' to apply to all animal food, not just RACs;
- Broaden ''activities . . . performed for the safe or effective storage'' to apply to all establishments that hold animal food, not just farms and farm mixed-type activities;
- Add ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged animal food as well as activities conducted on RACs; and
- Specify that holding facilities ''could'' include the listed types of facilities to clarify that some of these facilities might not meet the definition of a holding facility if they perform other activities not included in the definition of holding (e.g., if a grain elevator mixes different commodities to prepare animal food).

As discussed in section V.B, the revised definition of ''holding'' also would remove limitations on where the food is grown or raised (as a conforming change to the revised definition of ''farm'' found in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this issue of the **Federal Register**. The revised definition of ''holding'' would now be a one-part definition that applies to all facilities that hold animal food, rather than a two-part definition that first specifies activities that are within the definition regardless of the type of establishment and then specifies additional activities that would apply only to establishments that are farms or farm mixed-type facilities.

With this revised definition of ''holding,'' facilities such as grain elevators and silos would, in most cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 507.5(g)), because the definition would encompass activities performed as a practical necessity for the distribution of RACs. Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as facilities that package and sell seed for crops, but sell the leftover seed for animal food, also may satisfy these criteria for exemption.

With this revised definition of ''holding,'' facilities such as warehouses would, in many cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of packaged animal food that is not exposed to the environment (proposed § 507.10(a)), because the definition would encompass activities that are a practical necessity for product distribution (such as breaking down pallets and affixing tracking labels). We are adding ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged animal food as well as activities conducted on RACs. Although we are not adding more examples to reflect activities conducted on packaged animal food, the revised definition of ''holding'' also would include activities such as assembling sales kits and variety packs, because such activities are similar to breaking down pallets except that the order of activities is reversed.

F. Proposed Revisions to the Definition of ''Packing''

Just as there are some activities that are performed incidental to storing food for animals, there are some activities that are performed incidental to packing an animal food. For example, sorting, culling, and grading RACs could be an activity incidental to packing on a farm or farm mixed-type facility, whereas off-farm some sorting or similar activities such as culling or grading may be required to ensure that like items are packed together, or to remove damaged items. As another example, animal food may need to be conveyed (moved) about an establishment for the purpose of packing it, and may need to be weighed to ensure that appropriate amounts are packed. We tentatively conclude that we should revise the definition of ''packing'' so that it includes activities performed incidental to packing food for animals. In this document, we are proposing to revise the definition of packing to:

- Clarify that packing also includes activities performed incidental to packing animal food (e.g., activities performed for the safe or effective packing of that animal food (such as sorting, culling and grading));
- Provide that activities performed incidental to packing an animal food would apply to all establishments that pack animal food, not just to farms and farm mixed-type facilities; and
- Delete the provision, in the 2013 proposed rule for preventive controls, that packing would include activities (which may include packaging) traditionally performed on a farm on

RACs grown on a farm for storage or transport, because this issue would be addressed in the revised ''farm'' definition in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**.

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities

A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities

See the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, for discussion of comments.

B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition

We articulated the 2013 organizing principles for classifying on-farm activities to operate within the framework, already established in the section 415 registration regulations, in which an establishment that packs and holds others' RACs would be outside the ''farm'' definition and, thus, be required to register as a food facility. Our proposed revisions to the ''farm'' definition, found in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, would change that framework and, as a consequence, require that we reconsider those organizing principles.

Organizing Principles Nos. 1, 3, and 5 remain consistent with the proposed revisions to the ''farm'' definition. However, there would be no need to specify, in Organizing Principle No. 2, that activities that farms traditionally do relate only to their own RACs. In addition, Organizing Principle No. 4 would no longer apply, because the revised ''farm'' definition would no longer classify an activity as within (or outside of) the ''farm'' definition based, in part, on whether an activity is conducted on a farm's own RACs or on others' RACs. Therefore, we tentatively conclude it is appropriate to delete Organizing Principle No. 4 in light of the proposed revisions to the ''farm'' definition.

Table 4 shows our current thinking regarding the organizing principles applicable to the revised ''farm'' definition.

TABLE 4—UPDATED ORGANIZING PRINCIPLES THAT WOULD APPLY TO THE REVISED ''FARM'' DEFINITION

No.	Organizing principle
1	The basic purpose of farms is to produce RACs, and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.''
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Manufacturing/processing, packing, or holding food— whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

C. Changes to Classification of On-Farm Activities

We reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. See the Appendix to this document for a comprehensive table comparing the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed rule for preventive controls to our current thinking on the classification of these on-farm activities. As can be seen in the Appendix, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed rule for preventive controls) that could be classified in more than one way. For example, in the 2013 proposed rule for preventive controls, we classified ''removing stems and husks'' as a harvesting activity (e.g., if RACs are husked while they are being removed from the field). In this supplemental notice of proposed rulemaking, we also consider ''removing stems and husks'' to be a packing activity (e.g., if RACs are husked after the RACs have been removed from the field).

See Table 5 in this document for a list of the activity classifications that would change in light of the proposed revisions to the ''farm'' definition and our reconsideration of activity classification. As shown in Table 5, changes in activity classification as a result of the proposed revisions to the ''farm'' definition would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as an animal food facility. Importantly, the revised ''farm'' definition would not result in any new circumstance where a farm would now be required to register as a food facility.

Table 5 includes one activity (i.e., using pesticides on RACs as a packing activity) that we did not address in the 2013 proposed rule for preventive controls and excludes a number of activities (e.g., cooling RACs and coating RACs with wax/oil/resin) that were classified in the appendix of the draft risk assessment (Ref. 7) but are not performed on animal food.

Table 5 includes one activity (i.e., drying/dehydrating (incidental to holding)) that we now would classify in fewer ways than we did in the 2013 proposed rule for preventive controls. In the 2013 proposed rule for preventive controls, we classified drying/dehydrating (for purposes of storage or transport, rather than to create a distinct commodity) (e.g., drying alfalfa) as being either a packing activity or a holding activity, depending on when the drying/dehydrating took place. After reconsidering all of the activity classifications, we tentatively conclude that such drying/dehydrating should continue to be classified as ''holding,'' but does not constitute ''packing.'' We request comment on this narrowed classification of drying/dehydrating when the drying/dehydrating does not create a distinct commodity.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION

Activity	Classified in 2013 proposed rule for preventive controls	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed rule for preventive controls for animal food? [2]
Cooling	Harvesting; (§ 507.3); Mfg [1]/Processing (§ 507.3).	• Mfg/processing (e.g., cooling of processed animal food).	Acknowledge that field cooling of animal food RACs is not done.
Drying/dehydrating (incidental to holding).	Packing or Holding (Tables 1 and 15 of the draft risk assessment (RA)) (Ref. 7).	• Holding (e.g., drying hay or alfalfa)	Because we would no longer consider drying/dehydrating to be a packing activity.
Drying/dehydrating to create a distinct commodity (transforms a RAC into a processed animal food).	Mfg/Processing (Table 15 of the draft RA) (Ref. 7).	• Mfg/processing (e.g., drying grapes to create raisins, and drying herbs to create a distinct commodity) (because it transforms a RAC into a processed animal food) (but allowed within the farm definition).	Because we are including this specific mfg/processing activity within the ''farm'' definition, provided that there is no additional manufacturing/processing.
Filtering	Harvesting (§ 507.3)	• Harvesting (e.g., filtering honey)	Acknowledge that filtering is not done on animal food RACs.
Removing stems and husks	Harvesting (§ 507.3)	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that removing stems/husks can occur during more than harvesting operations.
Sifting	Harvesting (§ 507.3)	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that sifting can occur during more than harvesting operations.
Using pesticides on RACs.	Harvesting (Tables 1 and 15 of the draft RA discussed only fumigation) (Ref. 7).	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that pesticides may be used at various points in preparation of RACs
Washing	Harvesting (§ 507.3), and Mfg/Processing (§ 507.3).	• Harvesting (e.g., washing in the field was deleted). • Mfg/processing (e.g., during production of an animal food).	Acknowledge that field washing of animal RACs does not occur but washing during processing may occur.

[1] Mfg = Manufacturing.
[2] This table focuses on any change in classification in this document compared to the classification, in the 2013 proposed rule for preventive controls for food for animals, for activities conducted on a farm's own RACs. The proposed revisions to the ''farm'' definition would make the distinction between whether a farm conducted an activity on its own RACs or on others' RACs irrelevant.

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

A. The 2013 Proposed Exemptions

In the 2013 proposed rule, we described provisions of FSMA that direct us to (1) conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the ''farm'' definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64751 and 64752–64754); and (2) consider the results of that science-based risk analysis and exempt facilities that are small or very small businesses from these requirements (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of activities that we determine to be low risk involving specific animal foods that we determine to be low risk. Consistent with this statutory direction, we developed the draft risk assessment and made it available for public comment (Ref. 7 and 78 FR 64428); and proposed three exemptions for on-farm activity/animal food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed § 507.5(e), (f)(1), and (f)(2)).

B. Comments on the Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

Some comments received to the proposed rule for preventive controls for human food (78 FR 3646) request clarification on whether an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. Other comments recommend including additional on-farm packing and holding activity/food combinations, or on-farm manufacturing/processing activity/food combinations, as low-risk activity/food combinations eligible for inclusion in the proposed exemptions.

We are confirming that an establishment that conducts more than one activity/animal food combination listed in the proposed exemptions for on-farm low-risk activity/animal food combinations would be eligible for the exemption. The regulatory text is written in the plural (e.g., ''if the only packing and holding activities . . . that the business conducts are the following low-risk packing or holding activity/animal food combinations''; and ''if the only manufacturing/processing activities . . . that the business conducts are the following'').

We have not fully completed our review of comments on the 2013 proposed rule for preventive controls and the draft risk assessment. It is possible we may include additional activity/animal food combinations in these exemptions when we issue the final rule.

C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

The proposed revisions to the definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing,'' if finalized, would have three principal effects on the proposed exemptions.

- First, the proposed exemption for on-farm packing or holding of animal food by a small or very small business would no longer identify any packing or holding activities for any RACs, because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. The proposed exemption would continue to apply on-farm packing and holding of processed animal foods (e.g., packing and holding of silage when conducted by a farm mixed-type facility).
- Second, the proposed exemption for on-farm low-risk manufacturing/

processing activities conducted by a small or very small business would no longer distinguish between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility's own RACs.

• Third, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would be revised to eliminate activities, conducted on others' RACs, which would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding. For example, blending different lots of the same RACs such as whole grains would remain within the ''farm'' definition, and not be considered manufacturing/processing, regardless of whether the RACs being blended are the farm's own RACs or others' RACs. However, mixing forage to make silage would be considered manufacturing/processing and, thus, would continue to be considered a low-risk manufacturing/processing activity listed within the exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business.

We will update these proposed exemptions when we issue the final rule, after considering comments, and reaching a decision in light of those comments, on the proposed revisions to the definitions that impact the proposed exemptions for low-risk activity/animal food combinations.

IX. Proposed Applicability of Part 507 to the Holding and Distribution of Human Food By-Products for Use in Animal Food

Historically, many facilities that manufacture/process or pack human food also provide by-products from that human food production for use as animal food (Ref. 8). These by-products are a significant source of animal food or animal food ingredients. While these by-products may not be nutritious, suitable, or desirable for human consumption, they can be a source of energy and nutrition for certain species of animals, many of which have different digestive systems, physiology, and nutritional requirements than humans (e.g., ruminants such as cattle and sheep). The differences enable these animals to digest and metabolize the by-products in a way humans cannot.

Some of the by-products do not undergo further processing (such as drying, grinding, pelleting, etc.) at the human food facility before being used for animal food. Examples of these by-products include culls, peels, trimmings, and pulp from fruit and vegetable manufacturing/processing; chaff, bran, and middlings from grain milling; wet brewers grains from beverage brewing operations; and liquid whey from dairy facilities. Some of the by-products from these facilities are human food products that did not meet quality specifications for human food use. These out-of-specification products may be, for example, the wrong size, shape, or texture for human food, but are safe for use as animal food. Examples of these types of by-products include potato chips, cookies, bread, pastry products and pasta. Facilities may distribute the human food by-products directly for use as livestock food, or may distribute them to another facility for further processing for food for animals.

Human food facilities are currently subject to the current good manufacturing practices (CGMPs) regulations found in 21 CFR part 110 and would be subject to the proposed preventive controls for human food, found in proposed 21 CFR part 117, subpart C, if finalized. In the 2013 proposed rule for preventive controls for food for animals, we addressed human food facilities that also provide food for animals (78 FR 64736 at 64754). Proposed § 507.1(d) would have applied to these facilities and allowed them, for the animal food, the choice of complying with proposed part 507 for food for animals, subparts B and C as applicable, or proposed part 117 for human food, subparts B and C as applicable, so long as the facility addressed any hazards specific to the animal food.

In the 2013 proposed rule for preventive controls, we also addressed breweries and distilleries that make alcoholic beverages (78 FR 64736 at 64765). Many of these facilities provide the spent grains from the brewing or distilling process for use as animal food. In the 2013 proposed rule for preventive controls for human food (78 FR 3646), we proposed that subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' would not apply to certain alcoholic beverages and a very narrow set of prepackaged other food at alcoholic beverage facilities, based on the our interpretation of section 116 of FSMA. Section 116(b) of FSMA (21 U.S.C. 2206(b)) provides that section 116(a) of FSMA ''shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that [section 116(a) of FSMA] shall apply to a facility described in [section 116(a) of FSMA] that receives and distributes non-alcohol food, provided such food is received and distributed: (1) In a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.'' We stated in the proposed rule for preventive controls for food for animals that we were not aware of any animal food at any alcoholic beverage facility that would be exempt from proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' for food for animals as the spent grains for animal food is not an alcoholic beverage and is not in a prepackaged form as provided by section 116 of FSMA.

We have received comments from our stakeholders at public meetings and through comments to the proposed rule. Some comments stated that the requirements in proposed § 507.1(d) would potentially create a need for two separate food safety plans, one for human food and one for animal food. Some commented that requiring the facility to be subject to human food and animal food regulations would be a cost burden and as a result, some facilities would destroy their by-products, most likely by landfill, instead of complying with the rule for food for animals. Others commented that by-products used for animal food would not be a food safety concern because the human food is manufactured/processed or packed under CGMPs and many of these facilities also would be subject to the proposed rule for preventive controls for human food. Comments also said that the hazards that would be reasonably foreseeable for animal food (e.g., mycotoxins) would also be a hazard reasonably foreseeable for the human food and thus would be controlled by the facility by following CGMPs or implementing a food safety plan for the human food.

Based on comments reviewed to date and on comments made during public meetings, we considered other possible approaches to regulating packing and holding of by-products by a human food facility for distribution as animal food. We first conducted a review of the potential biological, chemical (including radiological), and physical hazards for these human food by-products used for animal food. We did not include hazards associated with human food by-products derived from animal products, including poultry and seafood (but did include dairy and egg products). We further limited our review to hazards associated with human food by-products that were not further processed

at the facility once separated from the human food because these processes could introduce hazards that would need to be addressed in a food safety plan. We reviewed the FDA Reportable Food Registry, published information about animal food recalls, as well as information from the CVM Feed Contaminants Program (Ref. 9). In addition, we conducted a scientific literature review on these by-products used as animal food (Ref.10).

Though there was not a large volume of data on human food by-products used as animal food, we tentatively conclude that while there are biological, chemical, and physical hazards that may be present in the human food by-products, the information reviewed indicates these hazards rarely occur.

For example, the reviewed information did not identify any instances of biological hazards in human food by-products (falling under the scope of the memorandum) used as animal food. Protein ingredients derived from meat, offal, poultry, and oil seed meal were found to be the most common source of biological hazards in animal food. Facilities providing by-products from these sources for use as animal food would be subject to proposed part 507, as explained in the discussion of proposed § 507.12 in this section. Chemical hazards such as mycotoxins or pesticides are known to be present in human food ingredients as well as animal food. We have tentatively concluded that these hazards would be controlled by the human food facilities for the human food, either under CGMPs or the proposed preventive controls for human food when finalized. The reviewed information did not identify any instances of chemical hazards from radionuclides in by-products used for animal food. The reviewed information did not identify any instances of physical hazards in human food by-products used as animal food except instances when the by-products were mistaken for trash and trash was added to them. We request comment, including additional data, on the findings of our research on biological, chemical, and physical hazards of human food by-product used as animal food.

Biological, chemical, or physical hazards in human food by-products used as animal food, as indicated by the reviewed information, were either hazards that are not known or reasonably foreseeable, are prevented or significantly minimized through the human food facility's compliance with current human food CGMP regulations, or would be prevented or significantly minimized through the human food facility's compliance with the proposed preventive controls regulations for human food, when finalized. The current CGMPs (and the proposed update to these requirements in the 2013 proposed rule for preventive controls for human food) as well as other applicable FDA human food safety regulations, are either the same as or more stringent than the proposed requirements for animal food. Therefore, we tentatively conclude that a facility's compliance with proposed subpart B of part 117 and all other applicable human food safety requirements of the FD&C Act and implementing regulations are sufficient to help provide animal food safety until the point of separation from the human food. We request comments on this tentative conclusion.

The review conducted did not include a search for hazards associated with seafood by-products. We request comment on how these by-products are used for animal food, including without further processing, and if these by-products should be subject to the requirements for animal food under proposed part 507.

Once the by-product is separated from the human food and is merely packed and/or held by the human food facility for distribution, the facility would need to take measures to ensure the animal food does not become contaminated. For example, during the time the animal food is held, the facility would need to ensure that the animal food is not treated like trash or garbage. The facility would need to protect the animal food from contamination with physical hazards such as floor sweepings containing glass or metal fragments and from chemical hazards such as equipment oil, cleaning chemicals, or pesticides used in the facility. Any of these could be inadvertently incorporated into the animal food if it was mistaken for trash.

As discussed in further detail in section X of this preamble, we are also proposing revisions to the proposed CGMPs for animal food. Particularly, we are proposing a section of CGMPs that would apply to the packing and holding of by-products in a human food facility for distribution as animal food. Once the by-product is separated from the human food, these proposed CGMPs for holding and distribution of the by-product intended for animal food would prevent or significantly minimize the known or reasonably foreseeable chemical and physical hazards that may occur after that separation. We tentatively conclude that biological and certain chemical hazards, such as mycotoxins and radionuclides, would not be known or reasonably foreseeable hazards in the by-products, given how unlikely those are to occur based on the review. We request comment on these conclusions. Based on the above conclusions, we have determined that, except for proposed § 507.28 regarding holding and distribution of human food by-products as animal food, proposed part 507 should not be applicable to these human food by-products used as animal food. Applying all the requirements set out in proposed part 507 for these by-products at human food facilities would not seem to provide any additional animal food safety benefit. Therefore, in this supplemental notice of proposed rulemaking, we are proposing revised requirements for human food facilities and the human food by-products they provide for animal food.

Proposed § 507.12 ''Applicability of this part to the holding and distribution of human food by-products for use in animal food,'' would address the applicability of part 507 to the holding and distribution of human food by-products for animal food. Except as provided in proposed § 507.12(b), the requirements of part 507 would not apply to by-products of human food production that are packed and held by that facility for distribution as animal food if the facility is subject to and in compliance with subpart B of part 117 and all other applicable human food safety requirements of the FD&C Act and implementing regulations and the facility does not further process the by-products intended for use as animal food. Proposed § 507.12(b) would require that once the animal food was separated from the human food, the facility would need to comply with proposed § 507.28 for the holding and distribution of that animal food.

A human food facility that further processes the human food by-product for animal food would be subject to proposed part 507 for those by-products. This would include by-products that undergo drying, pelleting, or heat-treatment such as dried brewers' grains, dried whey, or pelleted citrus pulp. These processes could introduce hazards that would need to be addressed in a food safety plan.

Proposed § 507.12 would not apply to human food products when contamination or adulteration has occurred that is materially related to food safety. We currently have two compliance policy guides that provide information to facilities that want to divert contaminated or adulterated human food for animal food use (Ref. 11, Ref.12). We handle the diversion requests on an individual basis and may not grant a request after review. Against the backdrop of proposed part 507, we

request comment on our compliance policy guides for diversion of adulterated human food products for animal food and whether we should include regulations for these types of requests.

Proposed § 507.12(b) would not apply to human food by-products derived from animal products (other than dairy and eggs), such as meat, offal, or poultry. We tentatively conclude that the hazards, particularly biological hazards, potentially associated with by-products from these animal products could be more substantial than those for the by-products addressed in the memorandum. We request comment on this conclusion.

Proposed § 117.145 of the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, addresses proposed corrective actions and corrections for human food. If a preventive control was found to be ineffective or was not properly implemented, steps would need to be taken to evaluate the food for safety and prevent affected food from entering into commerce if the facility cannot ensure the food is not adulterated. We request comment on how the facility would address by-products linked to the affected human food, especially if the preventive control problem was not discovered until after the separation of the by-products from the human food and possibly after the by-products have entered into commerce for use as animal food.

We are also proposing a conforming change to the 2013 proposed rule for preventive controls for human food part 117 by adding proposed § 117.95. This proposed section would contain the same requirements as those contained in proposed § 507.28, but would allow the human food processor to reference one part of the Code of Federal Regulations (i.e., part 117, if finalized) to determine the requirements applicable to the human food by-products used for animal food. We request comment on this approach. We also request comment on whether proposed § 507.28 should be removed from part 507, if finalized, if proposed § 117.95 is added to part 117, if finalized.

We request comment on these proposed requirements for human food by-products going to animal food use and request comment on any additional information available on the known or reasonably foreseeable hazards in human food by-products packed or held by human facilities for distribution as animal food. We also request comment on whether by-products from human dietary supplement and infant formula production are used for animal food, and if so, how these by-products should be addressed to help ensure safety of the animal food.

X. Proposed Revisions to Subpart B—Current Good Manufacturing Practice

In this supplemental notice of proposed rulemaking, we are proposing revisions to the requirements for current good manufacturing practice regulations (CGMPs) as proposed in the 2013 preventive controls rule for food for animals. We are proposing these revisions to the CGMPs based on stakeholder input and initial review of some comments received in response to the 2013 proposed rule for preventive controls. In the 2013 proposed rule for preventive controls, we discussed several sets of CGMPs that had already been developed by regulatory and animal health organizations, both domestic and international, that we believed could serve as a starting point for our proposed CGMPs for manufacturing, processing, packing, and holding food for animals (78 FR 64736 at 64772). These existing CGMPs included FDA's CGMP regulations for human food and medicated animal feed (21 CFR part 110 and part 225 respectively), the Association of American Feed Control Officials (AAFCO) model GMPs for feed and feed ingredients, best practices recommended by Codex for the feed industry, and the GMPs recommended in Publicly Available Specification (PAS) 222 (Ref.13, Ref. 14, Ref. 15). We concluded this discussion by saying that because of our experience and expertise with the human food CGMPs, we tentatively concluded that our human food CGMPs were the appropriate starting point for the animal food CGMPs. We then requested comment on whether CGMPs similar to those for human food are appropriate for animal food, and whether CGMP requirements appropriate for some types of animal food might be inappropriate for other types.

Specifically, a major concern we wanted to address with the proposed revisions is the difficulty of applying one set of CGMPs to both pet food facilities and livestock feed facilities. Some pet food facilities, depending on the type of product being manufactured, resemble human food facilities in that they use wet cleaning procedures to clean and sanitize food contact surfaces. They also must maintain high sanitation standards so that their finished product, which will be handled by pet owners, is free of pathogenic microorganisms. Livestock feed manufacturers on the other hand avoid the use of water and liquid cleaning compounds because of the need to maintain dry surfaces in facilities that predominantly move dry grains, oilseeds, and other dry ingredients through mixing operations that produce dry finished products. Sanitizing surfaces is thought to be unnecessary in most livestock feed facilities because the environment is much less conducive to microbial growth. We have tentatively concluded that these proposed revised CGMPs are more applicable to the animal food industry, provide flexibility for a wide diversity in types of animal food facilities, and still meet our objectives of establishing enforceable baseline standards for producing safe animal food. We request comment on this conclusion.

Proposed § 507.27 ''Holding and distribution'' originated from § 507.28 ''Warehousing and distribution'' in the 2013 proposed rule for preventive controls for food for animals. We have retitled the section ''Holding and distribution'' to better indicate the requirements would apply to animal food plants in general, not simply warehouses or distributors/distribution centers. The very general requirement previously proposed that animal food be protected against deterioration and biological, chemical, physical, and radiological contamination during storage and transportation was revised to be more specific.

Proposed § 507.27(a) would require that animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration of the animal food. Deterioration of animal food refers to loss of taste, aroma, or nutritive value typically associated with the animal food. For animal foods, taste and aroma are linked to palatability and deterioration in these properties can result in food refusal and wastage. Deterioration of nutritive value refers to loss of nutrients below amounts that the food is typically expected to provide. Both food refusal and consumption of animal food containing fewer nutrients than expected could result in states of undernourishment that may cause poor performance and ill health. Animals are typically fed the same food containing the same ingredients for prolonged periods, making consistent delivery of expected nutrient content important to prevent nutritional deficiencies or imbalances.

Contamination of a food can result from biological, chemical, or physical agents with biological and chemical being the agents most likely to contribute to deterioration of

palatability, aroma, and nutritive value of animal food. Microorganism contamination can lead to production of a chemical hazard, such as when animal food is contaminated with a mold that subsequently produces a mycotoxin in the animal food. Holding under appropriate conditions that minimize the potential for growth of undesirable microorganisms is particularly important when the animal food is not itself shelf stable or could be subjected to conditions that adversely impact product stability. (e.g., raw or frozen pet food). Proposed paragraph (a)(1) would require that containers used to hold animal food before distribution be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food.

Proposed paragraph (a)(2) would require that animal food held for distribution be held in a way that would prevent contamination from sources such as trash and garbage. This is particularly important when the animal food is held in bulk containers that could be mistaken for trash bins.

Proposed paragraph (a)(3) would require that labeling that identifies the product by the common or usual name be affixed to or accompany the animal food. The common or usual name is one that is readily recognized, for example, oats, corn, corn gluten meal, poultry by-product meal, meat, or dried whey. For byproducts from processing human food, the names in the AAFCO Official Publication are commonly used and recognized by industry and state feed programs, and in Compliance Policy Guide 665.100 ''Common or Usual Names for Animal Feed Ingredients,'' FDA has generally regarded the AAFCO feed ingredient definitions as establishing common or usual name of ingredients (Ref. 16). We tentatively conclude that this labeling requirement would enable the animal producer to use the animal food appropriately or an establishment receiving the animal food for further manufacture to use it appropriately. We also tentatively conclude that this labeling requirement would help prevent accidental comingling or mix-ups of products at the facility.

Proposed § 507.27(b) would require that shipping containers such as totes, drums, and tubs, as well as bulk vehicles, used to distribute animal food be inspected prior to use to ensure the container or vehicle will not contaminate the animal food. The purpose of this proposed paragraph would be to help ensure that such articles for holding and conveying animal food are not a source of contamination of animal food products.

Proposed § 507.27(c) would require that animal food returned from distribution be assessed for safety to determine the appropriate disposition of the animal food and be identified and segregated until assessed. The animal food plant or facility would not know how that animal food had been handled prior to return so the animal food could have been exposed to potential hazards, e.g., the growth of mycotoxin producing microorganisms if held in a high humidity area. This returned animal food could contain hazards resulting in contamination that could result in a food safety concern. If redistributed prior to assessment, depending on the nature and severity of the contamination, it could result in injury (or death) to animals.

Proposed § 507.27(d) would require that unpackaged or bulk animal food be held in a manner that does not result in cross contamination with other animal food. The purpose of paragraph (d) is to prevent instances of cross contamination such as food for swine that contains mammalian protein (that is prohibited for use in food for ruminants) contaminating food intended for cattle.

Revised proposed § 507.28 is now titled ''Holding and distribution of human food by-products for use as animal food.'' The revised proposed requirements are a subset of those in proposed § 507.27 and would specifically apply to human food processers that have certain by-products (as identified in proposed § 507.12) as a result of manufacturing human food and pack or hold the by-products for distribution for use as animal food. Since the human food would be subject to proposed part 117 subpart B and any other applicable FDA human food safety requirements of the FD&C Act and implementing regulations, we have tentatively concluded that hazards would be adequately controlled by these requirements in conjunction with the requirements of proposed § 507.28. Proposed § 507.28 would contain the CGMPs we tentatively conclude would be necessary for animal food safety once the by-products are separated from human food and become animal food.

As discussed in section IX, we are proposing a new § 507.12 for the applicability of part 507 to human food by-products used for animal food. Under proposed § 507.12, part 507 would not apply to by-products of human food production meeting the requirements of proposed § 507.12(a), except as provided in § 507.12(b). Proposed § 507.12(b) would require that the animal food from by-products identified in proposed § 507.12(a), be held and distributed by that facility in accordance with § 507.28 of part 507 and proposed § 117.95 of part 117.

The following is a brief summary of the proposed revisions to the CGMPs in proposed subpart B. In making the revisions, we also found it necessary to rearrange and retitle some of the sections, and make wording changes that we felt simplified the requirements and improved clarity. The details of these proposed requirements are in the re-proposed regulatory text for proposed subpart B.

- § 507.14—Personnel
  - Removed paragraphs (a)(1) and (a)(2) pertaining to ill employees and the requirement for employees to report illnesses to their supervisors. This change was made because we are not aware of any evidence of disease being transmitted from ill employees involved in manufacturing animal food to animals through the animal food.
- § 507.17—Plant and grounds
  - Primarily wording changes to consolidate requirements.
- § 507.19—Sanitary operations
  - Changed section title to ''Sanitation'';
  - Divided paragraph (a) into two categories—(a) pertaining to buildings, fixtures, and other physical facilities, and (b) pertaining to utensils and equipment;
  - Changed the wording in new paragraph (b) to say that utensils and equipment must be cleaned, maintained, and stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials;
  - Consolidated requirements, changed the order to group like requirements, and simplified the wording; and
  - Eliminated the requirement pertaining to single-service articles, which are not typically used in animal food facilities.
- § 507.20—Sanitary facilities and controls
  - The title was changed to ''Water supply and plumbing'';
  - This section contains only requirements related to the water supply and plumbing. The rubbish (reworded to trash and garbage) requirement was moved to § 507.19 Sanitation; and
  - Wording changes were made for simplification.

- § 507.22—Equipment and utensils
  - Requirements consolidated; and
  - Wording changes made for simplification.
- § 507.25—Processes and controls
  - Title changed to ''Plant operations'';
  - Changed paragraph (a)(1) to require that plant operations be conducted in accordance with the CGMPs in subpart B rather than in accordance with adequate sanitation principles;
  - Added requirements in paragraph (a)(9) that all animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of animal food;
  - Omitted the requirement in paragraph (b)(2) that raw materials and ingredients must not contain microorganisms injurious to human or animal health, or the raw materials and ingredients must be treated to eliminate them. This change was made because we do not intend that incoming raw materials and ingredients must be tested for pathogens, though the facility may choose to do so;
  - Requirements pertaining to processes and products used for human food but not animal food, such as heat blanching, batters, breading, sauces, and dressings were omitted; and
  - Requirements consolidated and wording simplified.
- § 507.28—Warehousing and distribution
  - Section renumbered to § 507.27;
  - Title changed to ''Holding and distribution'';
  - The very general requirement previously proposed that animal food be protected against deterioration and biological, chemical, physical, and radiological contamination during storage and transportation was revised to be more specific. We are now proposing that the following requirements apply to animal food held for distribution:
  - Animal food held for distribution must be held under conditions (for example, appropriate temperature, relative humidity, appropriate holding time) that minimize the potential for growth of undesirable microorganisms;
  - Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;
  - Animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage;
  - Labeling identifying the product by the common or usual name must be affixed to or accompany the animal food;
  - Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food;
  - Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed; and
  - Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food.
- § 507.28—Holding and distribution of human food by-products for use as animal food
  - The following new requirements were added:
  - Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:
  - Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;
  - Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage;
  - Labeling identifying the by-product by the common or usual name must be affixed to or accompany animal food;
  - Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food; and

We request comments on these proposed revisions to subpart B.

XI. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

A. 2013 Proposed Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

In general, in the 2013 proposed rule for preventive controls, we proposed that the owner, operator, or agent in charge of a facility:

- Prepare and implement a food safety plan, which would include documentation such as a written hazard analysis and various written procedures;
- Conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards to determine whether there are hazards that are ''reasonably likely to occur'';
- Identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified as ''reasonably likely to occur'' will be significantly minimized or prevented;
- Establish a written recall plan for animal food with a hazard identified as ''reasonably likely to occur'';
- Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed;
- Establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented;
- Take appropriate corrective action in the event of an unanticipated problem if a preventive control is not properly implemented and a specific corrective action procedure has not been established;
- Conduct certain verification activities; and
- Establish and maintain certain records.

These proposed provisions applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood (21 CFR part 123) and juice (21 CFR part 120), i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on CCPs to control hazards that are ''reasonably likely to occur.''

B. Comments on the ''Reasonably Likely To Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

Some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, about including the ''reasonably likely to occur'' approach in the 2013 proposed rules for preventive controls for human and animal food. The concern was that using the phrase ''reasonably likely to occur'' in two different contexts (i.e., within our HACCP regulations as well as in its proposed preventive controls regulations for human and animal food) would be confusing. Some comments received under the proposed rule for preventive controls for human food considered that the ''reasonably likely to

occur'' approach was already so closely linked to our HACCP regulations that the 2013 proposed rules for preventive controls for human and animal food would be interpreted as requiring that all necessary preventive controls be established at CCPs. These comments note that such an interpretation would be inconsistent with FSMA. For example, FSMA requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, *if any* (emphasis added) (section 418(c) of the FD&C Act). In addition, the definition of ''preventive controls'' in FSMA is broader than CCPs (section 418(o)(3) of the FD&C Act). The comments ask that we more explicitly provide for implementation of a range of preventive controls (not just at CCPs). These comments also express concern that a facility that already had established controls to address hazards—but not at CCPs—would need to revise its food safety plan, re-create any applicable records (e.g., various written procedures) to satisfy the recordkeeping requirements of the rule, which would add costs but no food safety benefits. For further discussion of these comments, please see supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

The 2013 proposed rule for preventive controls would not have required that all preventive controls be established at CCPs. However, we acknowledge that it could be confusing to use the same phrase ''reasonably likely to occur'' in both the our HACCP regulations and in the regulations we are proposing to establish to implement FSMA's requirements for hazard analysis and risk-based preventive controls, because the phrase ''reasonably likely to occur'' has been used as the basis for determining hazards that need to be addressed in a HACCP plan at CCPs.

Likewise, the 2013 proposed rule for preventive controls would not have limited a facility's flexibility to develop and implement a food safety system that was indeed risk-based. However, we acknowledge that some specific changes to the proposed regulatory text could help to clarify the risk-based nature of all provisions of subpart C.

We have not used the term ''prerequisite program'' in the proposed regulatory text because, like ''hazard reasonably likely to occur,'' it has a connotation with respect to our seafood and juice HACCP programs, that is, it connotes activities that a facility may do that have an impact on product safety but which are outside the scope of the regulatory program. However, comments are not suggesting that prerequisite programs that are essential to ensuring food safety should be outside the scope of this proposed regulatory scheme. In fact, comments asking that we recognize the role of prerequisite programs in the management of hazards point out that preventive controls include control measures that do not include CCPs and that companies would consider many of these to be prerequisite programs. We acknowledge that oftentimes preventive controls, other than those at critical control points, are important parts of a food safety system, and must therefore be included in the food safety plan that would be required by this proposed rule. We attempted to make that clear in the proposed requirement for preventive controls in § 507.36(a) by incorporating reference to ''controls, other than those at critical control points, that are necessary for food safety.''

We did not intend to require that a facility re-create or duplicate existing records associated with controls; we simply laid out in the 2013 proposed rule for preventive controls the activities for which we expect there to be records and the information we expect to find in those records.

Taking into account the comments we have reviewed so far, we are proposing a series of revisions to proposed subpart C and are reopening the comment period specifically with respect to these proposed revisions. These proposed revisions include:

- Eliminating the term ''hazard reasonably likely to occur'' throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term).
- Adding a new defined term, ''significant hazard,'' and, in general, using this new term instead of ''hazard reasonably likely to occur'' throughout the proposed regulations. ''Significant hazard'' would mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control.
- Defining ''known or reasonably foreseeable hazard'' in place of ''reasonably foreseeable hazard'' and clarifying that the new term means a hazard ''that has the potential to be associated with the facility or the food'' rather than ''a potential . . . hazard that may be associated with the facility or the animal food'';
- Providing additional flexibility to address concerns about re-writing existing plans or programs to conform with the requirement of the preventive controls rule by explicitly providing that:
- Preventive controls include controls, other than those at critical control points, that knowledgeable persons commonly recognize as appropriate for animal food safety;
- The preventive control management components (i.e., monitoring, corrective actions, and verification) depend on the nature of the control; and
- The recordkeeping requirements do not require duplication of existing records if those records contain all of the required information and satisfy the recordkeeping requirements of the regulation. Existing records may supplemented as necessary to include all of the required information. In addition, the required information does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by the preventive controls rule may be kept either separately or combined with the existing records.

The framework provided by ''significant hazard'' would reflect a two-part analysis on the part of a facility. First, the facility would narrow ''hazards'' to those hazards that are known or reasonably foreseeable—i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, as well as components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control.

The framework established by ''significant hazard'' also would incorporate the concept of risk by specifying that ''significant hazards'' are based on the outcome of a hazard

analysis. The hazard analysis would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk—i.e., the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

See the revised regulatory text for the proposed new definition of ''significant hazard'' (proposed § 507.3). The term ''significant hazard'' has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs. However, this term is not used in the seafood, juice or meat and poultry HACCP regulations, which focus on ''hazards reasonably likely to occur.'' We request comment on both the proposed name of the term and the proposed meaning of the term. See also the proposed new provision for the use of existing records (proposed § 507.212, which would be established in subpart F). Table 6 provides some examples of the flexibility that a facility would have in complying with the revised requirements that would be established in subpart C.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C

Flexibility related to . . .	Example
Controls other than those at CCPs	Dividing a facility into zones based on the risk with respect to contamination of product can be a preventive control, but would not have a CCP.
Controls other than those at CCPs	Preventive maintenance that inspects and changes preconditioner blades for a single screw extruder system at regular intervals may be considered a PC in some instances but would not have a CCP.
Circumstances that do not require process controls	Supplier controls.
Monitoring activity that generally would not require records	Monitoring for pieces of ferrous metal with magnets.
Corrections that generally would not require records	Re-cleaning inadequately cleaned animal food contact surfaces before start up.
Preventive controls that would not require validation	Zoning controls.
Preventive controls that would not require validation	Segregation of animal food intended for different species during storage.
Preventive controls that would not require validation	Training.
Preventive controls that would not require validation	Preventive maintenance.
Preventive controls that would not require validation	Refrigerated storage.
Corrective action that generally would not require verification	Replacement of equipment.

XII. Potential Requirements for Product Testing and Environmental Monitoring

A. Our Request for Comment on Including Requirements for Product Testing and Environmental Monitoring in a Final Rule

In the 2013 proposed rule for preventive controls, we described the statutory framework of FSMA for product testing and environmental monitoring as verification measures. We also requested comment on when and how product testing programs and environmental monitoring are an appropriate means of implementing section 418 of the FD&C Act (78 FR 64736 at 64836 and 78 FR 3646 at 3762–3765). We specifically requested comment on including requirements for product testing programs and environmental monitoring in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. Our discussions and questions about ''product testing'' focused on ''finished product testing.'' The Appendix contained extensive background on the role of testing as a verification measure in a modern food safety system (78 FR 64736 at 64834).

B. Product Testing

1. Comments on Product Testing

Some comments support product testing as a verification activity and make recommendations for what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan. Some of these comments emphasize that product testing would not be appropriate as a control measure. Other comments do not support including requirements for ''finished product testing'' as a verification measure, but support including requirements for ''product testing'' in the final rule if the focus is broader than ''finished product testing,'' the use of product testing is tied to risk, and the regulations provide flexibility in how product testing is used in a food safety plan. Commenters with varying views on the issue nonetheless requested that FDA include proposed regulatory text for consideration.

For a full discussion of comments received to the 2013 proposed rule for preventive controls for human food, see section X.B.1 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

2. Potential Requirements for Product Testing

We acknowledge that there are limitations to product testing. Nonetheless, product testing programs, when implemented appropriately based on the facility, the animal food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for product testing. Such requirements would be tied to risk and addressed through flexible written procedures that would address both test procedures and corrective action plans.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how product testing programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for product testing should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory

text would, if included in a final rule, establish requirements for:

- Product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control (proposed § 507.49(a)(2));
- Written procedures for product testing (proposed § 507.49(b)(2));
- Corrective action procedures for product testing (proposed § 507.42(a)(1)(ii)(A)); and
- Records of product testing (proposed § 507.45(b));

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. Consistent with the requests of the comments, proposed regulatory text would provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate by providing that the facility can take into account the facility, the animal food, and the nature of the preventive control (e.g., whether the control is a kill step) rather than prescribe product testing in specific circumstance, or require that all types of facilities (including warehouses) conduct product testing. For supplementary information relevant to product testing, see the 2013 proposed rule for preventive controls (78 FR 64736 at 64805–64806), the Appendix in that proposed rule (78 FR 64736 at 64834–64836), and section X.B in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

C. Environmental Monitoring

1. Comments on Environmental Monitoring

Some comments support environmental monitoring as a verification activity. In general, these comments recommend that the final rule specifically require environmental monitoring when ready to eat product (for human food) is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the animal food when it is exposed (note that under the 2013 preventive controls rule for animal food, the term ready to eat (RTE) is not used. All finished animal food is considered ready to eat, but it may not require packaging.) Comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk.

Some comments that generally support environmental monitoring as a verification activity nonetheless express concern about the potential for such requirements to be overly prescriptive. Comments particularly express concern about potentially prescriptive requirements for corrective actions if an environmental pathogen or appropriate indicator organism is detected.

Some comments do not support including requirements for environmental monitoring as a verification measure. Some of these comments assert that requirements for environmental monitoring would not be in accord with guidelines issued by the Codex Alimentarius Commission (Codex). Some comments note that environmental monitoring would not be relevant to all products, such as products that will be heat-treated or subject to a kill-step. Other comments note that environmental monitoring would not be relevant to facilities such as food distributors, due to the low likelihood of product contamination occurring in storage and distribution centers. Some of these comments express concern about broad requirements that would require environmental monitoring in a manner that was not risk-based, such as when an environmental pathogen is not reasonably likely to occur. Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for environmental monitoring for consideration.

2. Potential Requirements for Environmental Monitoring

Although the HACCP Annex of the Codex General Principles of Food Hygiene (Ref. 17) does not specifically recommend environmental monitoring as a verification activity in HACCP systems, the Codex General Principles of Food Hygiene (Ref. 18) does indicate that sanitation systems should be monitored for effectiveness and periodically verified, where appropriate, by microbiological sampling of environment and food contact surfaces, and regularly reviewed and adapted to reflect changed circumstances. Currently available data and information support the role of environmental monitoring in a food safety system that incorporates hazard analysis and risk-based preventive controls. (See, e.g., the 2013 proposed rules for preventive controls for animal food and human food (78 FR 64736 at 64806–64807 and 78 FR 3646 at 3764–3765 respectively) and the Appendices in the animal food and human food 2013 proposed rules (78 FR 64736 at 64834–64836 and 78 FR 3646 at 3812–3820 respectively.) See also and section X.C.2 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**). Environmental monitoring programs, when implemented appropriately based on the facility, the animal food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for environmental monitoring. The potential requirements would provide flexibility for animal food facilities to tailor their environmental monitoring programs based on risk. Environmental monitoring would be required in the specific circumstances where an animal food product is exposed to the environment prior to packaging, such as dog and cat food kibble, and the packaged animal food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the animal food when it is exposed. However, the potential requirements would not otherwise specify circumstances where environmental monitoring would be required and would instead require that the animal food facility conduct environmental monitoring as appropriate to the facility, the animal food, and the nature of the preventive control. The potential requirements would also not be prescriptive in the types of corrective actions needed in response to detecting an environmental pathogen or appropriate indicator organism in the environment; they would provide flexibility for facilities to establish and implement written corrective action procedures to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and, as necessary, prevent affected animal food from entering commerce.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how environmental monitoring is an appropriate means of implementing FSMA. We are seeking comment on whether requirements for environmental monitoring should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if

included in a final rule, establish requirements for:

- Performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen (proposed § 507.33(c)(2));
- Environmental monitoring, for an environmental pathogen (e.g., *Salmonella* spp) or for an appropriate indicator organism (e.g., Listeria spp for L. monocytogenes), as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control, if contamination of an animal food with an environmental pathogen is a significant hazard (proposed § 507.49(a)(3));
- Records of environmental monitoring (proposed § 507.45(b));
- Written procedures for environmental monitoring (proposed § 507.49(b)(3)); and
- Corrective action procedures for environmental monitoring (proposed § 507.42(a)(1)(ii))(B).

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. For supplementary information relevant to environmental monitoring programs, see the 2013 proposed rules for preventive controls for animal food and human food (78 FR 64736 at 64806–64807 and 78 FR 3646 at 3764–3765), the Appendices for animal food and human food (78 FR 64736 at 64834–64836 and 78 FR 17142 at 17143–17151), and section X.C.2 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

XIII. Potential Requirements for a Supplier Program

A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

In the 2013 proposed rule for preventive controls, we described the statutory framework of FSMA for supplier controls, i.e., the supplier verification activities that section 418 of the FD&C Act includes as an example of preventive controls. We also requested comment on when and how supplier verification activities are an appropriate means of implementing section 418 (78 FR 64736 at 64804–64809). We specifically requested comment on including requirements for supplier approval and other verification activities in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. The Appendix contained extensive background on the role of supplier programs in a modern food safety system (78 FR 64736 at 64836–64837).

B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

Some comments support including requirements for a supplier program in a final rule. These comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk, including risk inherent to raw materials and ingredients and risk that may be associated with a particular supplier (e.g., as reflected by the supplier's performance history). These comments provide many specific recommendations for what such requirements should—and should not—include. We summarize these recommendations in Table 7.

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM

Most comments support a requirement:	Most comments do not support a requirement:
For receiving raw material and ingredients from approved suppliers	For a written list of approved suppliers (because the list would be subject to frequent (perhaps daily) change).
For verification of a facility's immediate supplier	For verification of the supplier's supplier (because the facility has the greatest knowledge, leverage and ability to conduct meaningful oversight of its immediate supplier and because it is the supplier who is accountable to verify back one more step).
For records documenting that the basic requirements are being carried out.	For documents such as an underlying audit report (because of concerns about confidential information).
For audits as a verification activity, provided that the requirements are flexible and audits are not over-emphasized at the expense of other verification activities.	Prescribing the frequency of audits (particularly an annual frequency) (because an audit is only one tool and audits should be based on risk and on the performance of the supplier).
Limiting a supplier program to facilities that manufacture or process food.	Specifying that some hazards require more than one verification activity (because doing so would be too prescriptive and would not allow the facility the flexibility to determine the appropriate risk-based approach).
For oversight of a supplier program by a qualified individual	For a receiving facility to identify the regulations to which the supplier is subject (because the distinction would not be material to food safety).
That would be consistent with the Foreign Supplier Verification Program being established in a separate rulemaking.	
Specifying that a supplier program may be managed at a corporate level (rather than by specific facilities), because supplier programs are often managed at the corporate level. Some comments specifically recommend that inspection of a supplier program take place at the location where the program is managed, including at a corporate location rather than at an individual facility.	

Comments also address several other issues, such as whether the final rule should:

- Be limited to circumstances where a hazard is controlled by the supplier, or be required even if the hazard would be controlled by the receiving facility or by the receiving facility's customer.

• Include requirements for specific types of verification activities based only on the seriousness of hazards. Although some comments support such requirements, other comments do not because the basis should be risk (which includes probability as well as severity).

• Allow substitution of an inspection (e.g., by FDA) for an audit. Although some comments support such a substitution, others do not because they assert that an inspection and an audit are different in nature.

• Require a receiving facility to consider relevant regulatory information about the supplier. Although some comments support such requirements, others do not (e.g., because the information (which can be part of an overall supplier assessment) may not be available in a timely manner, is narrow in scope, and would diminish the importance of the supplier's food safety plan and the effectiveness of its implementation).

• Include requirements related to supplier non-conformance. Although some comments support such requirements, others maintain that supplier non-conformance would be better suited to guidance. Some comments specifically oppose a requirement for ''discontinuing use of the supplier'' and recommend flexibility for how a receiving facility would address supplier non-conformance.

• Provide for alternative verification requirements when a supplier is a qualified facility (which is subject to modified requirements; see proposed § 507.7 in the 2013 proposed rule for preventive controls). Although some comments support alternative requirements for suppliers that are qualified facilities, others express concern about whether alternative requirements can be practically implemented. Some comments state that the supplier verification requirements should not prevent facilities from sourcing ingredients from suppliers that are qualified facilities.

In general, comments that simply oppose including a supplier program in the final rule express concern about cost, ingredient diversity, and duplication of efforts. Some of these comments recommend that we issue guidance on supplier verification activities rather than establish requirements in the final rule. Some commenters, including those with varying views about the issue, nonetheless requested that FDA propose regulatory language for consideration.

C. Potential Requirements for a Supplier Program

Section 418 of the FD&C Act specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act). Supplier controls, when implemented appropriately, are an important preventive control that can ensure that significant hazards will be significantly minimized or prevented for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. Taking into account the comments reviewed so far, we are providing an opportunity for public comment on potential requirements for a supplier program as a preventive control. In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how supplier programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for a supplier program should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed FSVP rule. In that supplemental notice we request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and any preventive controls supplier verification provisions—as well as other aspects of the FSVP and preventive controls regulations—should be aligned in the final rules.

See the proposed regulatory text (proposed § 507.37 and the applicable definitions in proposed § 507.3) for the full text of such potential requirements. Briefly, the proposed regulatory text would, if included in a final rule:

• Establish definitions for terms used in the potential requirements for a supplier program (i.e., receiving facility; supplier; and qualified auditor) (proposed § 507.3)

• Establish a risk-based requirement for a written supplier program that:

• Would require, with some exceptions, a supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of raw material or ingredient (proposed § 507.37(a)(1) and(a)(2)); and

• Would not apply to raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance (proposed § 507.37(a)(1)(ii));

• Require verification activities, as appropriate to the hazard, and documentation of such activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis, from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 507.37(a)(3)(i));

• Require verification activities to verify that the hazard is significantly minimized or prevented, the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act, and the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 507.37(a)(3)(ii));

• Provide flexibility for a receiving facility to determine and document the appropriate verification activities for raw materials and ingredients from particular suppliers, based on a series of factors, except when there is a reasonable probability that exposure to a significant hazard will result in serious adverse health consequences or death to humans or animals (proposed §§ 507.37(b) and 507.37(c)(1)) (see next bullet);

• Require an annual audit as a verification activity when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, unless the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (proposed § 507.37(c)(2));

• Provide for an alternative verification activity when the supplier is a qualified facility (proposed § 507.37(c)(3));

• Provide for alternative verification activities when the supplier is a farm that would not be subject to the requirements in the final produce safety rule under proposed § 112.4 (proposed § 507.37(c)(4));

• Require that an audit be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience appropriate to perform the auditing

function (proposed § 507.37(d)(1)) and proposed § 507.53);

- Provide that inspection by FDA or an officially recognized or equivalent food safety authority may substitute for an audit (proposed § 507.37(e));
- Require action to address supplier non-conformance (proposed § 507.37(f)); and
- Require documentation of verification activities in records (listed in proposed § 507.37(g)), including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier's relevant food safety records (proposed § 507.37(g)(5), (g)(6), and (g)(7), respectively).

In addition, the potential addition of requirements for a supplier program would require conforming amendments to other provisions of the rule, including the requirements for a food safety plan, preventive controls, validation, verification of implementation and effectiveness, and the list of implementation records for subpart C (see proposed §§ 507.31(c)(3), 507.36(c)(3), 507.39(b), 507.47(b)(3), 507.49(a)(4), and 507.55(a)(4) respectively). For supplementary information relevant to a supplier program, see the 2013 proposed rule for preventive controls (78 FR 64736 at 64807–64809), Appendix (78 FR 64736 at 64836–64837) and section XI.C of the supplemental notice of proposed rulemaking for the preventive controls for human food published elsewhere in this issue of the **Federal Register**. In the following paragraphs, we provide additional information about the potential requirements for a supplier program.

Reflecting the risk-based (including severity as well as probability) nature of a potential supplier program, a receiving facility's program would be limited to those raw materials and ingredients for which the receiving facility has identified a significant hazard. As discussed in section XI.C, ''significant hazard'' would be defined in the rule. Under the definition, hazards are determined to be significant based on the outcome of a hazard analysis and, thus the determination would incorporate the concept of risk. In addition, a receiving facility would establish and implement a supplier program only when a significant hazard is controlled before receipt; a receiving facility would not be required to establish and implement a supplier program if the receiving facility, or the receiving facility's customer, controls the hazard (and the customer provides assurances as to the control). Under this risk-based approach, a pet food manufacturer generally would be required to establish a supplier program for hazards associated with the minerals it processes (which would be controlled by the supplier during manufacture), but a manufacturer of dry pet food would not be required to establish a supplier program for microbial hazards in poultry by-products that it uses to produce the dry pet food if it will control that hazard for the poultry by-products during manufacture of the pet food (e.g., through a heat kill step such as the extrusion process).

The potential supplier program would include requirements applicable to a ''receiving facility'' and the proposed definition of ''receiving facility'' would describe a receiving facility as a facility that manufactures/processes a raw material or ingredient that it receives from a supplier. A supplier would be defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consist solely of the addition of labeling or similar activity of a *de minimis* nature. The supplier could be an ''establishment'' rather than a ''facility'' because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a ''facility'' as that term would be defined for the purpose of this rule. Under this definition, a facility that packs or holds the animal food without any type of manufacturing/processing would not be a supplier. Under this approach, a facility would not be required to establish a supplier program for animal food products that it only packs or distributes. For example, a receiving facility might receive a raw material or ingredient from a distribution center that receives the raw material or ingredient from a manufacturing facility or a farm. The distribution center, which is the immediate previous source of the raw material or ingredient, would not be required to establish a supplier program and would not be considered the supplier; rather the supplier would be the manufacturer or the farm (which manufactured/processed the food or harvested the food that was provided to the distribution center and subsequently to the receiving facility). In such instance, if the receiving facility has identified a significant hazard for the raw material or ingredient, and that hazard is controlled by the supplier (the manufacturer or the farm), the receiving facility would establish verification activities related to the manufacturer or the farm that provided the raw material or ingredient to the distribution center.

If a facility receives an ingredient from a supplier, but the control of the hazard is by the supplier's supplier, under a potential supplier verification program, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard, i.e., the receiving facility would review the supplier's food safety records for its supplier's control of the hazard. For example, if a feed mill is receiving animal protein from a protein blender that receives meat and bone meal from a rendering facility, the feed mill could conduct verification activities related to the rendering plant controls at the rendering facility by reviewing the supplier program of, and verification activities conducted by, the protein blender for its supplier, the renderer (in addition to verifying the protein blender's control of pathogens).

We understand that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributers, between a receiving facility and the establishment that would be considered the supplier, which would make potential supplier verification very challenging under certain circumstances. We request comment on what verification activities would be appropriate for receiving facilities to conduct, should a supplier verification program be included in any final rule, when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. For example if a receiving facility is a feed mill that receives oats from a distributor, who receives grains from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms, where the hazards are being controlled, what supplier controls should be applied for the grains coming from the farms? We request comment on whether and how any potential supplier verification should address such situations.

In addition, we seek comment regarding whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain and Point B in the supply chain is a facility that only packs or holds

animal food, but does not manufacture/process animal food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain.

The potential supplier program would be included in the food safety plan and, thus, would be prepared (or overseen) by a qualified individual (see proposed § 507.31(b)). A supplier program could be established and maintained by a facility's corporate headquarters or parent entity. The recordkeeping requirements would specify that electronic records are considered to be onsite if they are accessible from an onsite location, and we expect that many records for the supplier program would be in electronic form (and thus easily retrievable by a facility during an inspection).

Rather than specifically require a written list of approved suppliers, the potential requirements would specify that the supplier program be written, and include verification activities, as appropriate to the hazard, and documentation of such activities, to ensure products are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use). Such a program could include, for example, written procedures for approving suppliers, for approving (or rejecting) specific raw materials and ingredients, and for documenting that raw materials or ingredients are only received from approved suppliers. The potential requirements would recognize that there can be circumstances that would require a facility to receive raw materials or ingredients on a temporary basis from an unapproved supplier (e.g., if there is a disruption in delivery of raw materials and ingredients from approved suppliers due to circumstances such as localized flooding or malfunctioning equipment). We request comment on examples of circumstances when it would be necessary and appropriate to receive raw materials and ingredients on a temporary basis from an unapproved supplier and on the types of verification activities that a facility should conduct on animal food from an unapproved supplier.

The potential requirements would provide flexibility for the verification activities that the receiving facility would conduct for raw materials and ingredients. With one exception, the receiving facility would have flexibility to select one or more of four possible activities: (1) Onsite audit; (2) sampling and testing of the raw material or ingredient, which could be conducted by either the supplier or the receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; and (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier. To determine which option is appropriate, the receiving facility could consider (1) the severity of the hazards; (2) where the preventive controls for those hazards are applied (such as at the supplier or the supplier's supplier); (3) the supplier's procedures, processes, and practices related to the safety of the raw materials and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food; (5) the supplier's animal food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation. Thus, a receiving facility would have flexibility to select a verification activity based on the circumstances.

The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In this circumstance, under the potential supplier program, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. The potential requirement for an annual audit is limited to when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. Further, the receiving facility could select less frequent audits or a different verification activity, if it documented its determination that the less frequent onsite auditing or other verification activity provides adequate assurance that the hazards are controlled. The potential recordkeeping requirements that would apply to audits would identify specific information that the records must provide about the audit, including the conclusions of the audit, but would not specify that the underlying audit report is part of the required documentation of an audit.

A person who conducts an audit would need to be qualified to do so. To be qualified, a person who conducts an audit (''qualified auditor'') would be required to satisfy the criteria for a ''qualified individual'' (a person who has successfully completed training in the development and application of risk-based preventive controls equivalent to that of an FDA-recognized standardized curriculum or is otherwise qualified through job experience to develop and apply a food safety system) and have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

The potential supplier program would require the receiving facility to know the FDA food safety regulations that apply to the supplier, and relevant information about the supplier's compliance with those regulations. The focus of section 418 of the FD&C Act is on preventing food safety problems rather than on reacting to them. Section 418 of the FD&C Act requires the owner, operator, or agent in charge of a facility to establish and implement preventive controls to significantly minimize or prevent known or reasonably foreseeable hazards. By specifying that supplier verification activities are a preventive control, section 418 requires the receiving facility to take necessary actions to ensure that raw materials and ingredients are not adulterated. To determine whether incoming raw materials and ingredients are adulterated, a receiving facility would need to know the regulatory framework that applies to the raw materials and ingredients, and to have confidence that its supplier is complying with that regulatory framework.

The potential supplier program would include provisions to address non-conformance by a supplier. This potential requirement would not prescribe when a particular corrective action (such as discontinuing a supplier) is necessary. A facility could substitute an inspection (whether by FDA or by the food safety authority of a country whose animal food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit. Even though inspection procedures and audit procedures are not identical, we tentatively conclude that a facility should have flexibility to determine whether an inspection could substitute for an audit based on characteristics such as the severity of

the hazard, how the supplier controls the hazard, and the supplier's performance history. For example, a facility that receives animal feed ingredients from a facility subject to the BSE feed regulations in 21 CFR 589.2000 may conclude that an FDA inspection for compliance with the BSE regulations (concluding that no action is indicated) provides adequate assurance that the facility is producing an animal food ingredient in compliance with the requirements of applicable FDA food safety regulations and is not adulterated under section 402 of the FD&C Act. For additional discussion of our reasons for tentatively concluding that it would be appropriate to substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit, see the discussion in the proposed FSVP rule (78 FR 45730 at 45758). In addition, we are asking for comment on whether it would be appropriate to substitute an inspection in another country (Country A) for an audit when, for example, it is the food safety authority of Country B (whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) that conducted the inspection in Country A.

The potential requirements would provide for alternative verification requirements when a supplier subject to the requirements of section 418 of the FD&C Act is a qualified facility subject to the requirements of proposed § 507.7. Section 418 provides different requirements for qualified facilities, which are reflected in the different potential verification requirements for such facilities. Although the potential requirements would allow a receiving facility to conduct an alternative verification activity when the supplier is a qualified facility, they would not require this.

Likewise, the potential requirements would provide for alternative verification requirements when a supplier is a farm that would not be subject to the requirements of proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm. Some of these farms would be not be subject to the requirements of proposed § 112.4 because they satisfy the criteria, in section 419(f) of the FD&C Act, for an exemption for direct farm marketing. Other farms would not be subject to the requirements of proposed § 112.4 because the crops they grow would not be covered by the proposed produce safety rule, either based on the findings of a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (see the discussion of this qualitative assessment of risk in the 2013 proposed produce safety rule, 78 FR 3504 at 3508 and 3522–3529) or because they account for a very small percentage of covered produce (see proposed § 112.4 and the discussion at 78 FR 3504 at 3549). Although the potential requirements would allow a receiving facility to conduct an alternative verification activity for such farms, they would not require this. Although the potential requirements would provide for alternative verification requirements for farms that would not be subject to the produce safety rule, we would not issue a final rule on such alternative verification requirements until we issue the final produce safety rule.

D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities

In the 2013 proposed FSVP rule, we tentatively concluded that it would be appropriate to address the independence of individuals conducting verification activities (78 FR 45730 at 45759). We proposed that an individual who conducts any verification activity must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity, and provided that this would not prohibit an importer, or the importer's employee, from conducting the verification activity (proposed § 1.506(g)). As discussed in the 2013 proposed FSVP rule, we considered such requirements necessary to prevent bias, or the appearance of bias, on the part of a person conducting a verification activity (78 FR 45730 at 45759).

We request comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements. For example, should such requirements be directed to a subset of persons who conduct verification activities (such as auditors) or should they be directed more broadly? Would a requirement such as in the 2013 proposed FSVP rule be appropriate, or would some other requirement be more appropriate (such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the activity)? What would constitute a financial interest in a company sufficient to constitute a conflict of interest for a person conducting a supplier verification activity (e.g., conducting an audit of that company or conducting laboratory tests of that company's food)?

XIV. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration

A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration

In the 2013 proposed rule for preventive controls, we announced our intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking rather than include them in the requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64745). We tentatively concluded that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we also acknowledged that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. We provided an example of this kind of hazard, i.e., the addition of the chemical melamine to certain food products, apparently to enhance the measured protein content and/or perceived quality of the product. We requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also requested comment on when an economically motivated adulterant can be considered reasonably likely to occur.

When we developed the 2013 proposed intentional contamination rule, we tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and for animal food (including hazard analysis, preventive controls, monitoring, corrective action, verification, and recordkeeping) rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism (see the 2013 proposed intentional adulteration rule, 78 FR 78014 at 78020). We also explained our view that the primary purpose of economically motivated adulteration is to obtain economic gain rather than to impact

public health, although public health harm may occur (78 FR 78014 at 78020).

B. Comments on Economically Motivated Adulteration

Some comments oppose including requirements directed to economically motivated adulteration in the preventive controls rule. These comments assert that the vast majority of economically motivated adulterants affect quality and value rather than safety. These comments also point out that the majority of food products could, in theory, be subject to economically motivated adulteration but that it would be difficult to determine if such adulteration is reasonably foreseeable. One comment recommends that we draw a clear distinction between hazards that are intentionally introduced and those that are not. Another comment expresses the view that food fraud is fundamentally different from both food safety and food defense. However, some comments do support including ''expected intentional adulterants'' in the preventive controls rule.

C. Potential Requirements To Address Economically Motivated Adulteration

Taking into account the comments we have reviewed so far for the proposed preventive controls rules for human food and for animal food, we are providing an opportunity for public comment on a potential requirement for the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain (see proposed § 507.33(b)(2)(iii) in proposed subpart C). In this section of this document, we are reopening the comment period with respect to our previous request for comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We are seeking comment on whether this preventive controls rule would be the most appropriate rule to address FSMA's requirements to address hazards that may be intentionally introduced (for purposes of economic gain) and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. We note that the preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 1) describes certain assumptions we are making about the preventive controls, and their implementation, that would be established and implemented by a facility that identifies a potential hazard that may be intentionally introduced for economic reasons as a significant hazard. We are seeking comment on alternative ways to control such hazards.

Under the definitions that would be established in the rule, a hazard would be an agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public (human or animal) health harm.

We believe that it is practicable to determine whether economically motivated adulteration is reasonably foreseeable. Importantly, we would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their animal food products. As discussed in the 2013 proposed intentional adulteration rule, we would expect facilities to focus on circumstances where there has been a pattern of such adulteration in the past, suggesting a potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product (78 FR 78014 at 78027). For example, in the 2013 proposed rule for preventive controls we discussed a widespread incident of economically motivated adulteration in which two ingredient suppliers added melamine, a nitrogen-rich industrial by-product (a non-protein nitrogen), to wheat gluten and rice protein concentrate to increase the apparent protein content (78 FR 64736 at 64746). The wheat gluten was imported by a U.S. broker and sold to U.S. pet food manufacturers and at least one distributor who then sold it to other pet food manufacturers. The melamine adulterated products later made their way into food for swine, poultry, and fish. This adulteration resulted in significant public health consequences for animals as well as concerns for human health from products produced from swine, poultry, and fish that had consumed melamine contaminated foods (72 FR 30014).

In light of this incident, a prudent person would include in its hazard analysis the potential for melamine to be an economically motivated adulterant in its animal food products when using certain protein ingredients for animal food and, based on the outcome of its hazard analysis, determine whether melamine is a hazard that must be addressed in the food safety plan.

There are other well-known substances that have been economically motivated adulterants and have potential to cause public (human and animal) health harm. The U.S. Pharmacopeial Convention (USP) has a free on-line food fraud database (Ref. 19) and a recent report from the Congressional Research Service provides additional information on economically motivated adulteration of food and food ingredients (Ref. 20).

XV. Provisions for Withdrawal of an Exemption for a Qualified Facility

A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility

In the 2013 proposed rule for preventive controls, we explained the provisions of FSMA that establish criteria for a facility to be a qualified facility, establish an exemption for qualified facilities, establish requirements for qualified facilities, and provide that we may withdraw the exemption otherwise granted to qualified facilities in specified circumstances (section 418(l) of the FD&C Act; see 78 FR 64736 at 64743). We proposed to establish:

- Definitions relevant to these provisions (proposed § 507.3);
- An exemption from the requirements for hazard analysis and risk-based preventive controls for qualified facilities (proposed § 507.5(d));
- Requirements for qualified facilities (proposed § 507.7); and
- Procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart D; the 2013 proposed withdrawal provisions) (see 78 FR 64736 at 64762, 64765, and 64810).

The 2013 proposed withdrawal provisions would:

- Specify the circumstances under which we would withdraw an exemption for a qualified facility (proposed § 507.60);
- Establish procedures for us to issue an order to withdraw the exemption, including information that would be in the order (proposed §§ 507.62 and 507.65);
- Establish procedures whereby a qualified facility may submit a written appeal of our order to withdraw an exemption (proposed § 507.67 and 507.69);
- Establish procedures for appeals, hearings, and decisions on appeals and hearings (proposed §§ 507.71, 507.73, 507.75, and 507.77); and
- Specify the circumstances in which an order to withdraw an exemption is revoked (proposed § 507.80).

B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption

For a full discussion on the comments received for provisions on withdrawal of an exemption for a qualified facility under the 2013 proposed rule for preventive controls for human food, see section XIII.B of the preamble for the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this **Federal Register.** See the revised regulatory text for proposed subpart D for the full text of the proposed requirements.

C. Proposed Revisions to the Content of an Order To Withdraw an Exemption

Based on comments reviewed to date for the proposed preventive controls rule for human food, which appear relevant to animal food, in this section of this document, we are reopening the comment period with respect to proposed § 507.65(d).

Some comments received under the 2013 proposed rule for preventive controls for human food recommend that the order explicitly state that the facility has the option to either comply with the order or appeal the order (with a request for an informal hearing) within 10 calendar days.

We tentatively conclude that it would be useful for the order to itself specify the two options that a facility has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions). Therefore, we are proposing to revise the requirements for the contents of an order to explicitly mention these two options. See the revised regulatory text of proposed § 507.65(d).

D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order

In this section of this document, we are reopening the comment period with respect to the timeframes in proposed §§ 507.65(d) and 507.67(a) and (c).

1. Comments

Some comments received under the 2013 proposed rule for preventive controls for human food ask us to specify that a facility's timeframe for taking action begins when the facility receives the order, not when we issue the order. Other comments address the timeframes for a facility to compile information needed to appeal an order for withdrawal. These comments assert that the proposed timeframe of 10 days is insufficient, and recommend timeframes such as 30 days or 90 days.

Some comments contrast the proposed 60-day timeframe to comply with the requirements for hazard analysis and risk-based preventive controls when a facility loses its exemption as a qualified facility with the timeframe that a facility would have to comply with these requirements when the final rule first becomes effective. As discussed in the 2013 proposed rule for preventive controls, we proposed compliance dates that would be 2 years and 3 years after the date of the final rule for small and very small businesses, respectively (78 FR 64736 at 64751). The comments assert that these two situations are parallel, because a qualified facility that has had its exemption withdrawn would be coming into compliance with the full requirements for hazard analysis and risk-based preventive controls for the first time. These comments recommend that we change the timeframes in the 2013 proposed withdrawal provisions to better align with the compliance dates contemplated by the proposed rule and by FSMA for small and very small businesses. Some of the comments recommend that a small business have 6 months, and that a very small business have 18 months, to comply with the order. Other comments recommend that any business (whether small or very small) have two years to comply with the order. Some of these comments recommend that the timeframe be tied to the date of the final determination rather than to the date of the order.

2. Proposed Revisions to Timeframes

We tentatively conclude that the nature of what a facility would need to do to comply with an order, i.e., comply with the full requirements for hazard analysis and risk-based preventive controls—makes the timeframes in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the proposed withdrawal provisions would only apply when a significant public health (human and animal) concern has been identified for a particular facility.

We also tentatively conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (§ 1.402).

Taking into account the comments reviewed so far for the proposed rule for preventive controls for human food, which appear relevant to animal food, we are proposing to require that a facility comply with an order to withdraw an exemption within 120 days of the date of receipt of the order. See the revised regulatory text for proposed §§ 507.65(d) and 507.67(a) and (c).

XVI. Definition of Very Small Business

A. The 2013 Proposed Options for Definition of Very Small Business

We proposed three options for the definition of a very small business based on total annual sales of animal food, adjusted for inflation: Option 1, $500,000; Option 2, $1,000,000; and Option 3, $2,500,000. The 2013 proposed rule for preventive controls contained several provisions relevant to very small businesses, including exemptions from subpart C in §§ 507.5(e) and 507.5(f) for very small (and small) facilities engaged only in specific types of on-farm activities involving low-risk activity/animal food combinations, the exemption in § 507.5(d) and requirements in § 507.7 for a very small business as a qualified facility, and extended time to comply with the rule. In defining a very small business, we took into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act (''Food Processing Sector Study'' (Ref. 21); see 78 FR 64736 at 64758–64759). In the 2013 proposed rule for preventive controls, we requested comment regarding the three proposed options for the definition of ''very small business.'' We also requested comment on whether a dollar amount of sales that is more than, or less than, the $500,000; $1,000,000; or $2,500,000 amounts would be appropriate.

B. Comments on the 2013 Proposed Options for Definition of Very Small Business

Comments support a variety of dollar limits of total annual sales of animal food for defining a very small business, including each of the three proposed options ($500,000, $1,000,000, and $2,500,000) as well as other dollar limits that we did not include as proposed options (e.g., less than $10,000). Some comments assert that very small facilities will incur a large portion of the costs associated with implementing the 2013 proposed rule for preventive controls rule because very small facilities lack experience with HACCP-based models.

Some comments support defining a very small business as one with total annual animal food sales up to $2,500,000. Some of these comments express concern that using lower dollar

sales amounts to define a very small business would discourage growth of very small processing facilities (especially those co-located on a farm), would unfairly burden very small facilities, and could cause them to fail due to the estimated high cost of compliance; whereas setting a higher dollar sales amount would encourage growth, innovation and diversification. Some of these comments note that adopting the threshold of $2,500,000 would establish that the full preventive controls requirements would apply to the businesses that produce the vast majority of animal food products and that modified requirements would apply to smaller businesses that represent the majority of producers but the minority of the animal food supply.

Other comments support no amount of annual animal food sales for defining very small business stating that the requirements should apply uniformly to all facilities. Some comments state that even a $2,500,000 threshold would result in very few of certain types of animal food facilities qualifying as a very small business.

C. Proposed Revisions to the Definition of Very Small Business

In this supplemental notice of proposed rulemaking, we are proposing the definition of very small business as a business that has less than $2,500,000 in total annual sales of animal food adjusted for inflation. The statutory construct does not prevent us from establishing a definition for very small business that would include more facilities than those that would be included under the statutory provision that considers sales to qualified end-users (section 418(l)(1)(C) of the FD&C Act). Section 418(n)(1)(B) of the FD&C Act directs FDA to define the term ''very small business'' for the purposes of determining whether a facility is a ''qualified facility'' eligible for modified requirements. Further, section 418(n)(1)(B) requires us to consider the Food Processing Sector Study for the purpose of defining ''very small business.'' FDA notes that section 418 of the FD&C Act does not otherwise limit how FDA may define ''very small business.''

We tentatively conclude that it is not necessary for the dollar limit in the definition of ''very small business'' to be $500,000 or less to protect public health (human and animal). In the 2013 proposed rule for preventive controls, we estimated the number of facilities that would be affected by the size specified in the definition of ''very small business.'' The size specified in the definition of ''very small business'' would affect the compliance dates, the exemptions for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity/animal food combinations and on-farm low-risk manufacturing/processing activity/animal food combinations (proposed §§ 507.5(d), (e), and (f), respectively) (see 78 FR 64736 at 64762–64763). As a group, businesses with less than $2,500,000 in total annual sales of animal foods produce less than two percent of all animal food produced in the United States when measured by dollar value. (In the 2013 proposed rule, this was stated as businesses with less than $2,500,000 in as total annual sales of animal food produce less than 20.8 percent of all pet food and animal feed produced in the United States when measured by dollar value (78 FR 64736 at 64760). This was an error and should have said less than 2 percent of all pet food and animal feed produced in the United States when measured by dollar value.) We acknowledge that this estimate of all animal food produced in the United States is higher than the estimates for lower dollar limits (less than one percent of all animal food produced in the United States, or less than one-half of one percent of all animal food produced in the United States, for limits of $1,000,000 or $500,000, respectively). Regardless, under the revised definition, the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness.

We tentatively conclude that the definition of very small business should exempt from the rule only a small percent of animal food to minimize the risk of foodborne illness and, thus, are proposing a very small business definition of $2,500,000, which would exempt less than two percent of the dollar value of animal food produced in the United States. We request comment on this tentative conclusion and whether we should consider other dollar limits for very small business.

A dollar limit in the definition of ''very small business'' greater than $500,000 would not necessarily exempt those companies whose practices would be most improved by complying with the requirements for hazard analysis and risk-based preventive controls. The Food Processing Sector Study (Ref. 21) concluded that there was no consistent pattern across food categories, including the pet food and animal feed categories, in terms of which sizes of establishments contribute most to foodborne illness risk (78 FR 64736 at 64758). Moreover, the facilities that would be classified as qualified facilities would be subject to modified requirements (see proposed § 507.7). Furthermore, all facilities that would be exempt from the requirements for hazard analysis and risk-based preventive controls would continue to be subject to the prohibitions in the Federal Food, Drug, and Cosmetic Act against causing animal food to be adulterated or misbranded and against distributing such animal food, and to inspection by FDA.

We are not proposing that the definition of ''very small business'' consider number of employees as well as dollar limits, be based on number of employees for consistency with the definition of ''small business,'' or be based on volume of animal food sold rather than on dollar limits associated with sales of animal food. There are two alternative sets of criteria to be a qualified facility. The criteria in section 418(l)(1)(C) of the FD&C Act are set out with regard to sales. We believe it is appropriate for the other criteria (related to being a ''very small business'') similarly to be related to sales. As discussed in the 2013 proposed rule for preventive controls, we proposed number of employees for the definition of ''small business'' in part because it would be the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR 121 for most food manufacturers. We continue to believe that the proposed definition of ''small business,'' based on number of employees, is appropriate.

We are not proposing that the definition of ''very small business'' consider the risk associated with the animal food manufactured, processed, packed, or held by the facility. The description ''very small'' addresses size of a business, not risk associated with animal food that the facility manufactures, processes, packs, or holds.

XVII. Other New and Revised Proposed Provisions

A. Proposed New Definitions

1. Proposed Definition of ''Pathogen''

In the 2013 proposed rule for preventive controls for food for animals, we proposed to define ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. Variations of the phrase ''microorganism of animal or human health significance'' appear in several places in the 2013 proposed

rule. To both simplify the regulations and use the same term (i.e., ''pathogen'') when we mean a microorganism of animal or human significance, we are proposing to define the term ''pathogen'' to mean a microorganism that is of public (human or animal) health significance and to replace variations of the phrase ''microorganism of animal or human health significance'' with ''pathogen'' throughout the regulations.

2. Proposed Definition of ''You''

We acknowledge the potential for confusion if the phrase ''owner, operator, or agent in charge'' applies to both plant management and operators in proposed subpart B and to the ''owner, operator, or agent in charge of a facility'' in proposed subpart C. Most of the provisions of proposed subpart B do not specify the role of ''plant management'' or the ''operator'' of a plant or establishment. To prevent confusion, we tentatively conclude it is prudent to retain terms such as ''plant management'' and ''operator'' in proposed subpart B.

However, we tentatively conclude that we can simplify the regulations directed to the ''owner, operator, or agent in charge of a facility'' in provisions in subparts A, C and D by using pronouns, without creating confusion, if we (1) define the term ''you'' to mean, for purposes of part 507, the owner, operator, or agent in charge of a facility and (2) limit use of the term ''you'' to provisions in proposed subparts A, C and D. See the revised regulatory text for the definition of you (in proposed § 507.3) and its use throughout revised subpart C.

3. Proposed Definition of ''Significant Hazard''

As discussed in section XI.C, we are proposing to delete the proposed definition ''hazard reasonably likely to occur'' and instead establish a definition for ''significant hazard.'' See the revised regulatory text in proposed § 507.3.

4. Proposed Definition of ''Known or Reasonably Foreseeable Hazard''

As discussed in section XI.C, we are proposing to delete the proposed definition ''reasonably foreseeable hazard'' and instead establish a definition for ''known or reasonably foreseeable hazard.'' See the revised regulatory text in proposed § 507.3.

5. Potential Definitions of ''Qualified Auditor,'' ''Receiving Facility,'' and ''Supplier''

As discussed in section XIII.C, we are providing an opportunity for public comment on potential requirements for a supplier program. If such requirements are included in a final rule, we would establish definitions for three terms used in the potential requirements for a supplier program, i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier.'' See the proposed regulatory text in proposed § 507.3.

B. Proposed Revisions to Definitions

In the 2013 proposed rule for preventive controls, we proposed to establish several new definitions.

1. Revised Definition of ''Hazard'' and ''Reasonably Foreseeable Hazard''

Some comments received under the 2013 proposed rule for preventive controls for human food recommended that we include radiological hazards as a subset of chemical hazards in the definition ''hazard.'' Although radiological hazards would not be common, we believe that facilities in the past have considered them as chemical hazards when conducting a hazard analysis for the development of HACCP plans. The revised regulatory text uses the phrase ''chemical (including radiological)'' in the definition of ''hazard'' and as applicable throughout the regulations. As a conforming change, we are proposing to revise the definition of ''reasonably foreseeable hazard'' to mean a potential biological, chemical (including radiological), or physical hazard that may be associated with the facility or the food.

2. Revised Definition of Environmental Pathogen

We proposed to define the term ''environmental pathogen'' to mean a microorganism that is of public (human or animal) health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. We identified Salmonella spp. and Listeria monocytogenes as examples of environmental pathogens. There was some concern that our proposed definition of ''environmental pathogen'' would capture organisms such as pathogenic sporeformers whose presence in and of itself would not constitute a risk to public (human or animal) health.

We are proposing to revise the definition of an environmental pathogen to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that animal food may be contaminated and may result in foodborne illness if that animal food is consumed (or in the case of pet food, handled by a human) without treatment at the facility to significantly minimize the environmental pathogen. The revised definition of ''environmental pathogen'' would specify that an environmental pathogen does not include the spores of pathogenic sporeformers and, thus, recognizes that consumption of animal food contaminated by the spores of a pathogenic sporeformer that is in the environment may not result in foodborne illness. For example, if animal food is contaminated with spores of C*lostridium botulinum,* the microorganism would not produce the botulinum toxin that causes illness unless these spores are subject to conditions that allow them to germinate into vegetative cells that produce the toxin. Pathogenic sporeformers are normally present in animal foods, and unless the foods are subjected to conditions that allow multiplication, they present minimal risk of causing illness.

C. Proposed Editorial Changes

The revised regulatory text includes several changes that we are making to make the requirements more clear and improve readability. We summarize the principal editorial changes in Table 8.

TABLE 8—PROPOSED EDITORIAL CHANGES

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout part 507	Substitute the term ''adequate'' for the term ''sufficient''	For the purposes of part 507, there is no meaningful difference between ''adequate'' and ''sufficient.'' We proposed a definition of ''adequate'' but did not propose to define ''sufficient.'' We tentatively conclude that the regulations will be clearer if we use the single term ''adequate'' throughout the regulations.

TABLE 8—PROPOSED EDITORIAL CHANGES—Continued

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout subparts A, C, and D.	Substitute the defined term ''you'' for ''owner, operator, or agent in charge of a facility''.	Improve clarity and readability.
507.31	Redesignate the section number from the original section number in the 2013 proposed preventive controls rule (proposed 507.30).	Accommodate insertions of new § 507.28 to subpart B.
507.31(d)	Specify that the food safety plan is a record that is subject to the requirements of subpart F within the requirements for the food safety plan (§ 507.31) rather than together with the requirements for other records required by the rule (§ 507.55).	Distinguish the requirements for the contents of the food safety plan from implementation records, which continue to be listed in § 507.55.
507.33(b)	Reordered the provisions in paragraph (b)	We tentatively conclude that it is more logical to specify what hazards must be considered (i.e., biological, chemical (including radiological), and physical) before specifying the reasons for how the hazards could get into the food products (i.e., naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain).
507.36	Shorten the title from ''Preventive controls for hazards that are reasonably likely to occur'' to ''Preventive Controls''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.
507.36(c)(1)	Rearrange the requirements for (i) parameters associated with the control of the hazard and (ii) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to be associated with process controls rather than be a standalone requirement.	It is more logical to place these requirements with process controls since their parameters and their values are associated with process controls.
507.36(c)(2) and 507.42(c)	Move requirements for corrections for sanitation controls from the requirements for preventive controls (proposed § 507.36) to the requirements for corrective actions (proposed § 507.42).	Improve clarity and readability.
507.38	Shorten the title from ''Recall plan for animal food with a hazard that is reasonably likely to occur'' to ''Recall plan''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''animal food with a hazard that is reasonably likely to occur''.
507.40	Redesignate the section number from the original section number in the 2013 proposed preventive controls rule (proposed § 507.39) and modify the language.	Accommodate insertions of new § 507.37 (supplier program) and new § 507.39 (preventive control management components) and reword to more closely match the statutory language.
507.45, 507.47, 507.49, and 507.50.	Move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 507.45) to separate sections (proposed §§ 507.47, 507.49, and 507.50, respectively).	Improve clarity and readability.
507.50(a)(4)	Revise the requirements for reanalysis of the food safety plan after an unanticipated event in which a preventive control is not properly implemented to refer to the requirements for corrective actions in light of such an event rather than repeat the full text of those requirements for corrective actions.	Simplify the presentation of requirements and reduce redundancy in regulatory text for inter-related requirements.
507.50(c)	Specify ''document the basis for the conclusion that no revisions are needed'' rather than ''document the basis for the conclusion that no additional or revised preventive controls are needed''.	Improve clarity and readability.
507.50(e)	Specify ''You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding'' rather than ''FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.''.	Improve clarity by specifying what the owner, operator, or agent in charge of the facility must do in certain circumstances rather than what FDA may require.
507.55	Change the title from ''Records required for subpart C'' to ''Implementation records''.	Accurately reflect the nature of the listed records after moving recordkeeping requirements for the food safety plan to § 507.31.
507.55(a)(3)(ii) and (iii)	Add ''verification of'' in front of ''monitoring'' and ''corrective actions''.	Distinguish these requirements for records applying to ''verification of monitoring'' and ''verification of corrective actions'' from other requirements for ''records of monitoring'' and ''records of corrective actions''.

D. Proposed Conforming Change to Proposed Part 117

As discussed in section IX, we are proposing a conforming change to proposed part 117, the preventive controls rule for human food. We are proposing to add § 117.95 to proposed subpart B that would add current good manufacturing practice requirements that would apply to human food manufacturers/processors when by-products from human food production are packed and held for animal food.

XVIII. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 1). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 1) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule, if finalized, would be a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

XIX. Paperwork Reduction Act of 1995

This supplemental notice of proposed rulemaking contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section with an estimate of the annual recordkeeping, reporting, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

Description: FDA is proposing to amend its 2013 proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals to add requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The amendments include potential provisions that would require facilities to establish and implement, as necessary, the following verification activities: product testing, environmental monitoring, and a supplier program. In addition, FDA is amending its proposed rule to require that the hazard analysis (HA) and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration (EMA) of animal food.

Description of Respondents: Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act. Generally, a facility is required to register if it manufactures, processes, packs, or holds food for consumption in the United States.

The information collection estimate for the supplemental proposal for preventive controls for food for animals may increase if the potential requirements (the addition of provisions for product testing, environmental monitoring, a supplier program, and identifying and evaluating any potential hazards caused because of economically motivated adulteration) are finalized. Additionally, proposed labeling requirements have been added for animal food, including labeling of human food by-products used for animal food.

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

Recordkeeping Burden

FDA estimates the burden for this information collection, should the potential provisions in this proposed rule be included in any final rule, as follows:

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN

21 CFR part 507, subpart C	Number of record-keepers [1]	Number of records per record-keeper	Total annual records	Average burden per record-keeping (in hours)	Total hours	Capital costs [2]	Operating and maintenance costs
Potential product testing written procedures (small pet food manufacturers) (potential § 507.49(a)(2))	20	0.33	6.6	5.33	35	.....	[1] $131,400
Potential product testing written procedures (small ingredient manufacturers) (potential § 507.49(a)(2))	10	0.33	3.3	5.33	18	.....	([4])
Potential environmental monitoring written procedures (potential § 507.49(a)(3))	105	0.33	35	5.33	187	.....	[2] 368,200
Potential supplier program written procedures (potential § 507.37(a)(2))	4,325	0.33	1,428	5.33	7,611	$4,018,100	[2] 162,200
§ 507.37(c)(3) and (c)(4) qualified or exempt suppliers' assurances	134	0.5	67	2	134	.....	.....
§ 507.33(b)(2)(iii) written HA for EMA	4,325	0.33	1,428	3	4,284	$627,800	[2] 4,227,300
§ 507.33(b)(2)(iii) updating written HA for EMA	4,325	0.5	2,163	0.1	216	([5])	([5])
§ 507.49(a)(4)(ii) verification—review of records	952	12	11,424	0.5	5,712	.....	[1] 258,400
Total	.....	.....	.....	.....	18,197	$4,645,900	5,147,500

[1] From 2014 PRIA (Ref. 1).
[2] These numbers were obtained from FDA economics staff.
[3] Costs for product testing and EMA are broken out across 2 rows.
[4] Included in row 1 costs.[3]
[5] Included in row 6 costs.[3]

Table 9 indicates the potential hourly and cost burden for complying with the supplemental notice of proposed rulemaking: i.e., product testing, environmental monitoring, the supplier program, economically motivated adulteration, and verification review of records.

Should the potential provisions in this proposed rule be included in any final rule, we estimate 8,130 facilities would be subject to subpart C—Hazard Analysis and Risk-Based Preventive Controls. We also estimate the number of non-qualified facilities would be 4,325 and the number of qualified facilities would be 3,805.

Should the potential product testing provision be included in a final rule, product testing would be an activity for verification of implementation and effectiveness FDA estimates that 102 non-qualified small pet food manufacturers and 67 non-qualified small ingredient suppliers exist. The Eastern Research Group (ERG) cost model reports that only these categories contain facilities subject to Subpart C that do not currently test animal food products for *Salmonella* but that might do so under proposed § 507.49(a)(2). The ERG also estimates that 20% of facilities are out of perfect compliance and would need to develop and record written procedures. In Table 9, to obtain the amount for total records for product testing for small pet food manufacturers, 20 small pet food manufacturers (recordkeepers) (20% of 102) multiplied by 0.33 records per recordkeeper (1 written procedure during the 3-year PRA approval period) equals 6.6 total records annually. Then, to obtain total hours, 6.6 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA subject matter experts (SMEs)) equals 35 hours annually. For small ingredient manufacturers (Table 9, row 2), to obtain the total number of records, 10 recordkeepers (20% of 67 rounded down to 10) multiplied by 0.33 records per recordkeeper (1 written procedure during the 3-year PRA approval period) equals 3.3 total records. Then, to obtain the total number of hours, 3.3 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA SMEs) equals 18 hours annually.

Should the potential environmental monitoring provision be finalized, FDA estimates 105 recordkeepers would need to include environmental monitoring procedures as a verification activity, creating one written procedure per facility. In Table 9, to obtain the number of annual records, 105 recordkeepers multiplied by 0.33 environmental monitoring procedures per facility (over 3 years of the PRA approval period) equals 35 annual records. Then, to obtain the total number of hours, 35 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA SMEs) equals 187 total hours annually.

Should the potential supplier program previously discussed be included in a final rule, a receiving facility establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient, a receiving facility would not be required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards, for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards, or for which the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The potential procedures for the supplier program would need to be written should this provision be included in a final rule. FDA estimates that all facilities would need to develop a written supplier program. In Table 9, to obtain the total number of records, 4325 recordkeepers (keeping written records of written assurances) multiplied by 0.33 records per facility per year (during the three year PRA approval) equals 1,428 records annually. Then 1,428 multiplied by 5.33 hours to create each record (time needed according to FDA SMEs) equals 7,611 total hours annually.

Should the potential supplier program be finalized, suppliers that would be qualified facilities and suppliers that are farms not subject to the requirements in proposed 21 CFR part 112 regarding the raw material or ingredient that the receiving facility receives from the farm would need to create at least every 2 years a written assurance to be given to their receiving facility customers. This assurance would need to describe the processes and procedures that the supplier is following to ensure the safety of the animal food. FDA estimates that these few suppliers would require about two hours to create this documentation to be submitted to their receiving facility customers. To obtain the total number of records, 134 recordkeepers multiplied by 0.5 records per year (submitted every 2 years) equals 67 records annually. To obtain the total number of hours, 67 records multiplied by 2 hours per record equals 134 hours annually.

For proposed § 507.33(b)(2)(iii), FDA estimated an average of 3 hours additional time for the hazard analysis in order to account for the possibility of economically motivated adulteration. To obtain the total number of records, 4,325 recordkeepers multiplied by 1 record per facility (or 0.33 records annually for the 3-year PRA approval) for writing and developing the initial hazard analysis equals 1,428 total records annually. Then 1,428 multiplied by an additional 3 hours per hazard analysis equals 4,284 total hours annually. In the 2013 PRIA (Ref. 22), FDA estimated that on average, facilities will need to update their hazard analysis every two years. In addition, FDA estimates 0.1 hours additional time would be needed to update the hazard analysis. To obtain the total number of records, 4,325 recordkeepers multiplied by 0.5 records per year equals 2,163 total records. Then 2,163 total records multiplied by 0.1 hours per record equals 216 hours annually.

The potential supplier program would require verification of implementation and effectiveness, including review of records for product testing, environmental monitoring, and supplier verification activities. Based on the responses to the ERG survey of human food production facilities, FDA estimates that the percentage of animal food facilities without these verification records varies from about 39% of those with fewer than 20 employees, to less than one percent for those with 100 or more employees. This equates to about 952 facilities, all of which would be out of compliance with the record review verification requirements.

To obtain the total number of records, 952 multiplied by 12 records per year (or 1 record per month) equals 11,424 records. To obtain the total number of hours, 11,424 records multiplied by 0.5 hours per record (time needed according to FDA SMEs) equals 5,712 hours annually.

Reporting Burden

There is no reporting burden in this information collection.

Third Party Disclosure Burden

Under proposed § 507.27(a)(3), labeling identifying the product by the common or usual name would need to be affixed to or accompany the animal food. The number of disclosures per respondent and the average burden per disclosure in Table 10 below were obtained by consulting FDA SMEs.

FDA estimates the burden for this information collection as follows:

TABLE 10—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 507, subpart B	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 507.27 Holding and distribution	8130	20	162,600	0.25	40,650

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

There are 8,130 facilities which each would have 20 sets of labeling per facility to affix to or accompany the animal food for a total number of 162,600 disclosures (labeling) per year. To obtain total number of hours, 162,600 disclosures multiplied by 0.25 hour to print labeling, and affix to the containers if labels, equals 40,650 total hours annually.

Under proposed § 507.28(a)(3), labeling identifying the human food by-product by the common or usual name would need to be affixed to or accompany the animal food. The number of disclosures per respondent and the average burden per disclosure in Table 11 were obtained from FDA SMEs.

FDA estimates the burden for this information collection as follows:

TABLE 11—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 507, subpart B	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 507.28(a)(3) Holding and distribution of human food by-products for use as animal food	40,798	2	81,596	0.25	20,399

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

According to FDA SMEs, an estimated 60 percent of the 67,996 domestic human food manufacturing facilities (Ref. 23) or 40,798 facilities would be affected, with two sets of labeling per facility per year expected, equals 81,596 disclosures (labeling). To obtain the number of total hours, 81,596 disclosures multiplied by 0.25 hours to prepare labeling, and affix to the containers if labels, equals 20,399 total hours.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this supplemental notice of proposed rulemaking to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XX. Analysis of Environmental Impact

As with the 2013 preventive controls proposed rule, we determined under 21 CFR 25.30(j) that this supplemental notice of proposed rulemaking is an action of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 24). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXI. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XXII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. Preliminary Regulatory Impact Analysis,'' 2014.
2. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, November 21, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm368989.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
3. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, November 25, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm368988.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
4. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, December 6, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm371844.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
5. FDA, ''Update on Proposed Rules under the FDA Food Safety Modernization Act (March 19, 2014).'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm389696.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
6. Cooperative Extension Service, Division of Agricultural Sciences and Natural Resources, Oklahoma State University; USDA, Federal Grain Inspection Service; USDA, Extension Service; USDA, Animal and Plant Health Inspection Service, ''Stored Product Management,'' Circular No. E–912, January 1995. Available at *http://entomology.k-state.edu/doc/extension-crop-pests/E912_All_Stored_Product_May3.pdf* (accessed on September 5, 2014).
7. FDA, ''Draft Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2013.
8. Grasser, L.A., J.G. Fadel, I. Garnett, and E.J. DePeters, ''Quantity and Economic Importance of Nine Selected By-Products Used in California Dairy Rations,'' *Journal of Dairy Science,* 78:962–971, 1995.
9. FDA, ''Compliance Program 7371.003, Feed Contaminants'' December 13, 2005.
10. FDA Memorandum, ''Biological, Chemical, and Physical Hazards Associated With Human Food By-Products Used for Animal Food,'' 2014.
11. FDA, ''Compliance Policy Guide Sec. 675.100 Diversion of Contaminated Food for Animal Use'' Available at *http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074693.htm.* Revised: March 1995, Page Last Updated: December 15, 2009 (accessed on September 5, 2014).
12. FDA, ''Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use'' Available at *http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074694.htm.* Revised: March 1995, Page Last Updated: December 15, 2009 (accessed on September 5, 2014).
13. Association of American Feed Control Officials (AAFCO), ''Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients'', In: AAFCO Official Publication, 210–215, 2010.
14. Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO), ''Good Practices for the Feed Industry—Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding—Section 3 Good Production Practices,'' 2010.
15. British Standards Institute (BSI), ''Publicly Available Specification (PAS) 222:2011 Prerequisite Programmes for Food Safety in the Manufacture of Food and Feed for Animals,'' 2011
16. FDA, ''Compliance Policy Guide Sec. 665.100 Common or Usual Names for Animal Feed Ingredients'' Available at

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074687.htm. Revised: March 1995, Page Last Updated: December 16, 2009 (accessed on September 5, 2014).
17. Codex Alimentarius Commission, ''Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application. Annex to CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
18. Codex Alimentarius Commission, ''General Principles of Food Hygiene, CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
19. U.S.Pharmacopeial Convention, ''U.S. Pharmacopeial Convention (USP) Food Fraud Database,'' March 6, 2014. Available at *http://www.usp.org/food-ingredients/food-fraud-database* (accessed on September 5, 2014).
20. Congressional Research Service, ''Food Fraud and Economically Motivated Adulteration of Food and Food Ingredients,'' January 10, 2014. Available at *http://www.fas.org/sgp/crs/misc/R43358.pdf.* (accessed on September 5, 2014).
21. Muth, M. K., C. Zhen, M. Coglaiti, S. Karns, and C. Viator, ''Food Processing Sector Study, Contract HHSF 22320101745G, Task Order 13, Final Report,'' 2011.
22. FDA, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Food for Animals—Preliminary Regulatory Impact Analysis,'' 2013.
23. FDA, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food—Preliminary Regulatory Impact Analysis,'' 2013. Docket No. FDA–2011–N–0920.
24. FDA, ''Re-proposal of Select Provisions of the Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,'' 2014.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1 amend the entry in paragraph (b)(2), as proposed to be amended on October 29, 2013 (78 FR 64736), to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.85 (part 507, subpart D) relating to withdrawal of exemption applicable to a qualified facility.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 3. The authority citation for 21 CFR part 117, as proposed to be added on January 16, 2013 (78 FR 3646), continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 4. In part 117, as proposed to be added on January 16, 2013 (78 FR 3646), add § 117.95 to read as follows:

§ 117.95 Holding and distribution of human food by-products for use in animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing/processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the by-product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

PART 507—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

■ 5. The authority citation for part 507, as proposed to be added on October 29, 2013 (78 FR 64736), continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350c, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

■ 6. Amend § 507.1, as proposed to be added on October 29, 2013 (78 FR 64736), by removing paragraph (d).

■ 7. Amend § 507.3, as proposed to be added on October 29, 2013 (78 FR 64736), as follows:

■ a. By removing definitions for ''Hazard reasonably likely to occur'' and ''Reasonably foreseeable hazard'';

■ b. By alphabetically adding new definitions for ''Known or reasonably foreseeable hazard''; ''Pathogen''; ''Qualified auditor''; ''Receiving facility''; ''Significant hazard''; ''Supplier''; and ''You''; and

■ c. By revising the definitions for ''Environmental pathogen''; ''Harvesting''; ''Hazard;'' ''Holding''; ''Packing''; and ''Very small business''.

The additions and revisions read as follows:

§ 507.3 Definitions.

* * * * *

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and

Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Pathogen means a microorganism of public (human or animal) health significance.

* * * * *

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2).

* * * * *

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

* * * * *

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of food for animals, adjusted for inflation.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

■ 8. Amend § 507.5, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) to read as follows:

§ 507.5 Exemptions.

(a)(1) Except as provided by paragraph (a)(2) of this section, this part does not apply to establishments (including ''farms'' as defined in § 1.227 of this chapter) that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(2) If a ''farm'' or ''farm mixed-type facility'' dries/dehydrates raw agricultural commodities to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

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■ 9. Subpart A, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.12 to read as follows:

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use in animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if:

(1) The human food processor is subject to and in compliance with subpart B of part 117 of this chapter, and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food processor does not further manufacture/process the by-products intended for animal food.

(b) The animal food from by-products identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

■ 10. Revise subpart B, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

Subpart B—Current Good Manufacturing Practice

Sec.
507.14 Personnel.
507.17 Plant and grounds.
507.19 Sanitation.
507.20 Water supply and plumbing.
507.22 Equipment and utensils.
507.25 Plant operations.
507.27 Holding and distribution.
507.28 Holding and distribution of human food by-products for use in animal food.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against contamination of animal food, animal

food-contact surfaces, or animal food-packaging materials.

(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 507.17 Plant and grounds.

(a) The grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

(b) Buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. This includes:

(1) Providing adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Being constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Providing adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food; and locating and operating fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food;

(4) Providing adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured/processed, packed, or stored, and areas where equipment or utensils are cleaned;

(5) Providing safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against animal food contamination in case of glass breakage; and

(6) Protecting animal food stored outdoors in bulk by any effective means, including:

(i) Using protective coverings;

(ii) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and

(iii) Checking on a regular basis for pests and pest infestation.

§ 507.19 Sanitation.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning.

In addition:

(1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.

(2) In wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

(d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is manufactured/processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in the plant's operations;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in laboratory testing procedures.

(2) Toxic materials described in paragraph (d)(1) of this section (for example cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Effective measures must be taken to exclude pests from the manufacturing/processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(f) Trash and garbage must be conveyed, stored, and disposed of in a way that protects against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests.

§ 507.20 Water supply and plumbing.

(a) The water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing/processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies,

equipment, or utensils, and avoid creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing/processing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils:

(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) The design, construction, and use of equipment and utensils must preclude the contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

(5) Equipment in the animal food manufacturing/processing area that does not come into contact with animal food must be designed and constructed in such a way that it can be kept in a clean condition.

(b) Holding, conveying, and manufacturing/processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way that does not contaminate animal food.

(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature monitoring device.

(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way that animal food is not contaminated.

§ 507.25 Plant operations.

(a) Plant management must ensure that:

(1) All operations in the manufacturing/processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Containers holding animal food, including raw materials, ingredients, or rework, accurately identify the contents;

(3) The labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species;

(4) Animal food-packaging materials are safe and suitable;

(5) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(6) Reasonable precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food packaging materials;

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and

(8) Animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(9) All animal food manufacturing/processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination of animal food.

(b) Raw materials and ingredients:

(1) Must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients must be inspected upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize soil or other contamination; and

(iii) Raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration.

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans;

(3) And all rework, must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated; and

(4) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(c) For the purposes of manufacturing/processing operations, the following apply:

(1) Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing/processing, packing, and holding;

(2) Measures taken during manufacturing/processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling aw) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is

protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects animal food against contamination;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;

(6) Animal food that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

§ 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany the animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(c) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(d) Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food.

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

■ 11. Revise subpart C, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

Sec.

507.31 Food safety plan.
507.33 Hazard analysis.
507.36 Preventive controls.
507.37 Supplier program.
507.38 Recall plan.
507.39 Preventive control management components.
507.40 Monitoring.
507.42 Corrective actions and corrections.
507.45 Verification.
507.47 Validation.
507.49 Verification of implementation and effectiveness.
507.50 Reanalysis.
507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.
507.53 Requirements applicable to a qualified individual and a qualified auditor.
507.55 Implementation records.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.36(b);

(3) The written supplier program as required by § 507.37(a)(2).

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a) You must:

(1) Identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards; and

(2) Develop a written hazard analysis.

(b) The hazard identification must consider:

(1) Hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances; and

(iii) Physical hazards; and

(2) Hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen.

(d) The hazard evaluation must consider the effect of the following on

the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors.

§ 507.36 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and animal food:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the applicable control:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(2) Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supplier controls that include the supplier program as required by § 507.37;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls that include any procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 507.37 Supplier program.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

(A) There are no significant hazards;

(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or

(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

(2) The supplier program must be written.

(3) The supplier program must include:

(i) Verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and

(ii) Verification activities, as appropriate to the hazard, and documentation of these activities, as required by paragraph (b) of this section, to verify that:

(A) The hazard is significantly minimized or prevented;

(B) The incoming raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in an animal food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;

(2) Where the preventive controls for those hazards are applied for the raw material and ingredients such as at the supplier or the supplier's supplier;

(3) The supplier's procedures, processes, and practices related to the safety of the raw material and ingredients;

(4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food;

(5) The supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c)(1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities determined by the

receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

(i) Onsite audits;

(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility;

(iii) Review by the receiving facility of the supplier's relevant food safety records; or

(iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.

(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by § 507.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 507.3; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d)(1) An onsite audit of a supplier must be performed by a qualified auditor;

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e)(1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted; and

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(g) The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4):

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

(4) Documentation demonstrating that products are received only from approved suppliers;

(5) Documentation of an onsite audit. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

(6) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

(7) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and

(iii) Documentation that the review was conducted by a qualified individual.

(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.

(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;

(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:

(i) The documentation that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with

applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

§ 507.38 Recall plan.

(a) For animal food with a significant hazard you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect animal and human health;

(3) Conduct effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food (e.g., reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying).

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.36 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supplier program established in § 507.37 is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.40 Monitoring.

(a) As appropriate to the preventive control you must:

(1) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) You must monitor the preventive controls with adequate frequency to provide assurance that the preventive controls are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i).

§ 507.42 Corrective actions and corrections.

(a) As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a specific corrective action procedure has not been established;

(ii) A preventive control is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the sanitation controls in § 507.36(c)(2)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be

documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the preventive control:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the significant hazards are adequate to do so as appropriate to the nature of the preventive control.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control significant hazards; and

(3) Need not address:

(i) The sanitation controls in § 507.36(c)(2);

(ii) The supplier program in § 507.37; and

(iii) The recall plan in § 507.38.

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control:

(1) Calibration of process monitoring and verification instruments;

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within a week after the records are created; and

(ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

(b) As appropriate to the facility, the food, and the nature of the preventive control, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1)(ii).

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan:

(1) At least once every 3 years;

(2) Whenever a significant change is made in the activities conducted at your facility if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(3) Whenever you become aware of new information about potential hazards associated with the animal food;

(4) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(5) Whenever you find that a preventive control is ineffective.

(b) You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production.

(c) You must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed.

(d) A qualified individual must perform (or oversee) the reanalysis.

(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the

growth of, or toxin formation by, microorganisms of animal or human health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.53 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Review of records (§ 507.49(a)(4)); and

(4) Reanalysis of the food safety plan (§ 507.50(d)).

(b) A qualified auditor must conduct an onsite audit (§ 507.37(d)).

(c)(1) To be a qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Records that document the monitoring of preventive controls;

(2) Records that document corrective actions;

(3) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(4) Records that document the supplier program; and

(5) Records that document applicable training for the qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

■ 12. Section 507.60, as proposed to be added on October 29, 2013 (78 FR 64736), is revised to read as follows:

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, import alert, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

■ 13. Section 507.62, as proposed to be added on October 29, 2013 (78 FR 64736), is revised to read as follows:

§ 507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

■ 14. Amend § 507.65, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (d) to read as follows:

§ 507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.

* * * * *

(d) A statement that the facility must either:

(1) Comply with subpart C of this part on the date that is 120 calendar days after the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

* * * * *

■ 15. Amend § 507.67, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraphs (a) and (c) to read as follows

§ 507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) If you receive an order under § 507.65 to withdraw an exemption applicable to that facility under § 507.5(d), you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

* * * * *

(c) If you appeal the order, and FDA confirms the order, you must comply with applicable requirements of this part within 120 calendar days of the date of receipt of confirmation of the order.

■ 16. Amend § 507.69, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) introductory text and paragraph (a)(1) to read as follows:

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(d), you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of receipt of the order;

* * * * *

■ 17. Amend § 507.71, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) to read as follows:

§ 507.71 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of receipt of the order.

* * * * *

■ 18. Subpart D, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.85 to read as follows:

§ 507.85 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the animal food manufactured/processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both §§ 507.60(a)(1) and 507.60(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

§ 507.100 [Redesignated as § 507.200]

■ 19. Redesignate § 507.100, as proposed to be added on October 29, 2013 (78 FR 64736), as § 507.200.

■ 20. Revise § 507.102, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

§ 507.202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§§ 507.106 and 507.108 [Redesignated as §§ 507.206 and 507.208]

■ 21. Redesignate §§ 507.106 and 507.108, as proposed to be added on October 29, 2013 (78 FR 64736), as §§ 507.206 and 507.208, respectively.

■ 22. Subpart F, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.212 to read as follows:

§ 507.212 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be

duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

The supplemental notice of proposed rulemaking that is the subject of this document includes a discussion of our reconsideration of the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities (see the discussion and Table 5 in section VII.C). Table 1 in this Appendix compares the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed rule for preventive controls to our current thinking on the classification of these on-farm activities as a result of the proposed revisions to the ''farm'' definition.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES

Classification	Examples using the 2013 proposed ''farm'' definition*	Examples using the proposed revisions to the ''farm'' definition
Harvesting Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as animal food. Harvesting does not include activities that change a RAC into processed animal food.	• Cooling RACs*** (activity deleted because is not done on RACs for animal food) • Filtering RACs*** (activity deleted because is not done on RACs for animal food) • Gathering RACs • Removing stems and husks from RACs • Shelling RACs • Sifting RACs • Threshing RACs • Trimming of outer leaves from RACs • Washing RACs*** (activity deleted because is not done on RACs for animal food)	• Gathering RACs • Removing stems and husks from RACs • Shelling RACs • Sifting RACs • Threshing RACs • Trimming outer leaves from RACs
Packing: Placing animal food in a container other than packaging the animal food and activities performed incidental to packing an animal food (e.g., activities performed for the safe or effective packing of that animal food (such as sorting, culling and grading)), but does not include activities that transform a RAC into a processed animal food.	• Coating RACs with wax/oil/resin for the purpose of storage or transport*** (deleted because is not done on RACs for animal food) • *Drying RACs for the purpose of storage or transport*** (would change to only be classified as ''holding'') • Labeling RACs • Mixing RACs • *Packaging a farm's or farm mixed-type facility's own RACs*** (would no longer be limited to ''own RACs'') • Putting RACs or individual unit cartons into non-consumer containers • Sorting/grading/culling RACs • Stickering RACs	• Labeling RACs • Blending RACs (e.g., blending different lots of the same RAC such as whole grains that does not result in a new commodity) • *Packaging RACs regardless of ownership*** (expanded to include others' RACs) • Putting RACs or individual unit cartons into non-consumer containers • *Removing stems and husks from RACs*** (add'l classification) • *Sifting RACS*** (add'l classification)**** • Sorting/culling/grading RACs • Stickering RACs • *Using pesticides on RACs*** (add'l classification)
Holding: Storage of animal food and activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that food, and activities performed as a practical necessity for the distribution of that animal food (such as blending of the same commodity and breaking down pallets)). Holding does not include activities that change a RAC into a processed animal food.	• Drying/dehydrating RACs during storage (incidental to *packing or* storing when the drying/dehydrating does not create a distinct commodity)** (would no longer be incidental to packing, would only be incidental to holding) • Fumigating RACs during storage • Sorting/culling/grading RACs • Storing food	• Drying/dehydrating RACs (incidental to storing when the drying/dehydrating does not create a distinct commodity) • Fumigating RACs during storage to control pests • Sorting/culling/grading RACs • Storing animal food

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES—Continued

Classification	Examples using the 2013 proposed "farm" definition*	Examples using the proposed revisions to the "farm" definition
Manufacturing/Processing: Making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, milling, grinding, extracting, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.	• Artificial ripening *** (this activity deleted because is not done on animal food) • Canning • Chopping • Coating RACs for purposes other than storage/transport *** (this activity deleted because is not done on animal food) • Cooking • Cooling • Coring • Cracking • Crushing • Cutting • Distilling • Drying/dehydrating RACS to create a distinct commodity • Extracting • Formulating • Freezing • Grinding • Homogenizing • Infusing • Irradiating • Labeling (other than RACs) • Milling • Mixing • Packaging (other than RACs) • Pasteurizing • Peeling • Rendering • Roasting • Salting • Slaughtering and post-slaughter operations • Slicing • Smoking • Sorting, culling, grading (not incidental to packing or holding) • Trimming • Washing	• Canning • Chopping • Cooking • Cooling • Coring (*except field coring*)** (because field coring would be newly classified as harvesting) • Cracking • Crushing • Cutting • Distilling • Drying/dehydrating RACs to create a distinct commodity • Extracting • Formulating • Freezing • Grinding • Homogenizing • Infusing • Irradiating • Labeling (other than RACs) • Milling • Mixing • Packaging (other than RACs) • Pasteurizing • Peeling • Rendering • Roasting • Salting • Slaughtering and post-slaughter operations • Slicing • Smoking • Sorting, culling, grading (not incidental to packing or holding) • Trimming • Washing

* Examples were included in Table 4, Table 5, and/or proposed §§ 507.3 and 507.5(e) and (f) in the 2013 proposed rule for preventive controls and/or in the Draft Risk Assessment (Ref. 1).

** Activities listed in italics represent a change between the 2013 "farm" definition and our current thinking in light of the proposed revisions to the "farm" definition.

*** Activities deleted because they are not typically performed in animal food.

**** add'l = additional.

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. This reference is also available electronically at *http://www.regulatons.gov*.

1. FDA, "Draft Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2013.

[FR Doc. 2014–22445 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P